

Risk Factors Comparison 2025-02-27 to 2024-02-29 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

The following is a summary of the significant risk factors that could materially impact our business, financial condition or future results, including risks related to our businesses, our international operations, our regulatory environments, ownership of our common stock, and other general risks: • ~~Management previously identified material weaknesses in our internal control over financial reporting, some of which resulted in errors in previously issued financial statements. Although these material weaknesses have all been remediated as of December 31, 2023, should they recur, or if we experience additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements for public companies, which could cause the price of our common stock to decline or limit our access to the capital markets.~~ • We may be subject to additional litigation and regulatory examinations, investigations, proceedings or court orders as a result of or relating to the 2022 internal investigation which included certain financial reporting matters, which is now complete, and if any of these items are resolved adversely against us, it could harm our business, financial condition and results of operations. • ~~Lack of global standardized processes, centralization of transaction management and / or failures to execute could result in control deficiencies and adversely impact management's assertions and financial reporting.~~ • We rely heavily on information and technology to operate both our businesses and our technology dependent product solutions portfolios, and any cyber incidents with respect to our information and technology infrastructure, whether by deliberate attacks or unintentional events, could harm our operations and have a material impact on our business and financial results. • Evolving governmental oversight of the use of personal information, cross- border data transfer restrictions and the use of **emerging technologies, including AI**, as well as other technology regulations, may adversely affect our business. • We may be unable to develop innovative products and solutions to stimulate customer demand. • Damage to our reputation or brand could negatively impact our business, financial condition or results of operations. • Our ongoing business operations may be disrupted for a significant period of time, resulting in material operating costs and financial losses. • We may be unable to execute key strategic initiatives due to competing priorities and strategies of our distribution partners and other factors, which may result in financial losses and operational inefficiencies. • **Our success of our business depends in part on achieving our strategic objectives, including through acquisitions, dispositions exiting of businesses, and divestitures or strategic investments may result in financial results that are different than expected and initiatives create certain risks for our business and operations.** • We may fail to realize the expected benefits of our strategic initiatives, including ~~recently executed~~, **announced**, or potential future restructuring and other business transformation efforts. • We have recognized substantial goodwill and indefinite- lived intangible asset impairment charges and may be required to recognize additional goodwill and indefinite- lived intangible asset impairment charges in the future. • Our failure to protect our proprietary technology could have an adverse impact on our competitive position. • Our financial results may be adversely impacted if our products **or services** are found to infringe upon the intellectual property rights of others. • Changes in our credit ratings or macroeconomic impacts on credit markets may increase our cost of capital and limit financing options. • ~~A breach of the covenants under~~ **Our indebtedness could adversely affect our financial condition and prevent us from fulfilling** our debt instruments outstanding from time to time could result in an event of default under the applicable agreement. • We may not be able to repay our ~~or contractual obligations~~ outstanding debt if we do not generate sufficient cash flow to service our debts and cross default provisions may be triggered due to a breach of covenants under our existing indebtedness. • Our foreign currency hedging and cash management transactions may be ineffective or only partially mitigate the impact of exchange rate fluctuations, exposing us to unexpected volatility. • Due to the global nature of our business, including increasing exposure to markets outside of the United States, political or economic changes or other factors could harm our business and financial performance. • ~~Changes~~ **Management previously identified material weaknesses** in ~~or our~~ interpretations of tax rules **internal control over financial reporting**, operating structures ~~some of which resulted in errors in previously issued financial statements. These material weaknesses were all remediated as of December 31, transfer pricing regulations~~ **2023. If we experience additional material weaknesses in the future, we** ~~country profitability mix and regulations may~~ **be unable to accurately and timely report financial results or comply with the requirements for public companies, which could cause the price of our common stock to decline or limit our access to the capital markets.** • ~~Lack of global standardized processes could result in control deficiencies and~~ **adversely affect impact management's assertions and financial reporting.** • We may be subject to additional litigation and regulatory examinations, investigations, proceedings ~~our or effective tax rate~~ **court orders relating to the completed 2022 internal investigation regarding certain financial reporting matters. If any of these items are resolved adversely to us, it could harm our business, financial condition and results of operations.** • We may be unable to obtain necessary product approvals and marketing clearances. • ~~Our doctor~~ **Changes in tax rules or interpretations of tax rules, operating structures, transfer pricing regulations, country profitability mix and regulations and tax investigations, audits, or other proceedings that we are subject to may harm our business, financial condition and results of operations, including by adversely affecting our effective tax rate.** • We voluntarily suspended the sale and marketing of our direct - directed, ~~direct to customer clear-~~ **consumer Byte aligner business could systems and impression kits, and subsequently determined to cease offering these aligners to new patients while repurposing Byte technologies and capabilities to support other products within our aligner portfolio. As a result, we have experienced a material impact on our results of operations, and we may be required adversely affected by challenges to our business model take additional significant impairment charges if we are unsuccessful in** ~~or our efforts~~ **by new state actions restricting our ability to reposition Byte provide our products and services**

~~in certain states.~~ • Inadequate levels of reimbursement from governmental or other third- party payors for procedures using our products may cause our revenue to decline. • Challenges may be asserted against our products due to real or perceived quality, health or environmental issues. • If we fail to comply with laws and regulations relating to health care fraud, we could suffer penalties or be required to make significant changes to our operations, which could adversely affect our business. • Our business is subject to extensive, complex and changing domestic and foreign laws, rules, regulations, self- regulatory codes, directives, circulars and orders which, if not complied with, ~~subjects~~ **subject** us to civil or criminal penalties or other liabilities. • The market price for our common stock may continue to be volatile as a result of a number of factors, including **our** quarterly operating results. • Certain provisions in our governing documents, and of Delaware law, may make it more difficult for a third party to acquire us. • Our business may be adversely affected by changes in global economic conditions, including inflation, rising interest rates, and supply chain shortages. • Talent gaps and failure to manage and retain top talent may impact our ability to manage our operations, execute strategic initiatives and grow ~~the~~ **our** business. • We face the inherent risk of legal actions, including litigation, product liability claims, and other regulatory or compliance matters. • Climate change and related natural disasters could negatively impact our business and financial results. • Expectations relating to environmental, social and governance considerations may expose us to potential liabilities, increased costs, reputational harm, and other adverse effects on our business. Below is a full description of each of such significant risk factors. **RISKS RELATED TO OUR BUSINESSES We rely heavily** **INTERNAL CONTROLS** A description of the material..... the material weaknesses identified under Item 8 **on information technology** this Form 10- K, or other material weaknesses or deficiencies identified in the future, could result in a misstatement of accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis or cause us to fail to meet our obligations under securities laws, stock exchange listing rules, or debt instrument covenants to file periodic financial reports on a timely basis. Any material weaknesses identified in the future could adversely affect investor confidence in our financial statements and cause the price of our common stock to decline or limit our access to the capital markets. As previously disclosed in 2022, we voluntarily contacted the SEC to advise that the Audit and Finance Committee was conducting an independent investigation regarding certain financial reporting matters, and we are continuing to cooperate ~~with~~ **operate** with the SEC. The SEC’s investigation is ongoing. Additionally, several securities class action lawsuits were filed against us following our announcement on May 10, 2022 of the Audit and Finance Committee’s internal investigation. As a result of the previously reported material weaknesses in internal control over financial reporting which have been remediated as of December 31, 2023, we may face additional litigation and regulatory examinations, investigations, proceedings or **our businesses** court orders, including additional cease and desist orders **product portfolios**, the suspension of trading of our securities, delisting of our securities, the assessment of civil monetary penalties and other equitable remedies. Our management has devoted and may be required to further devote significant time and attention to these matters. If any **cyber incidents** of these matters are resolved adversely against us, it could harm our reputation, **operations and have a material impact on our** business ; **and** financial condition and results of operations. Additionally, while we cannot estimate our potential exposure to these matters at this time, we have already expended a significant amount of time and resources investigating the claims underlying and defending these matters and expect to continue to expend our resources to conclude these matters. Accordingly, the ongoing SEC investigation and any related litigation could result in distraction to management and entail risks and uncertainties, the outcome of which could adversely affect our results of operations and our reputation. For further information, see Note 21, Commitments and Contingencies, discussing the securities class action lawsuits, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10- K. We currently have disparate systems, including Enterprise Resource Planning (“ERP”) systems, across the organization which may result in the potential inability to obtain and analyze business data and increases in budgets due to higher costs stemming from system upgrades, and may pose business partner connection challenges. Non- standardized processes and ineffective controls could result in an inability to aggregate and analyze data in a timely and accurate manner and may lead to inaccurate or incomplete financial and management reporting and delays in financial reporting to management, regulators and / or shareholders. Inaccurate or incomplete financial reporting and disclosures could also result in noncompliance with applicable business and regulatory requirements and the incurring of related penalties or fines. As a result, the data required to manage the business may not be complete, accurate or consistent, resulting in the potential for misleading or inaccurate reporting for key business decisions. We continue to focus on standardizing our processes, improving our financial systems, maintaining effective internal controls and centralizing transaction management and execution so as to provide continued assurance with respect to our financial reports, support the continued growth of the business, and prevent financial misstatement or fraud. In 2023, we began a process of implementing a new global ERP system, which will upgrade and standardize our existing information systems. However, this new ERP system will take several years to implement, will require significant resources to integrate with the Company’s other business processes, and even at its completion may not be fully successful in providing standardization sufficient to address these risks once completed. For further information, refer to the risk factor titled “ We may fail to realize the expected benefits of our strategic initiatives, including recently executed or potential future restructuring and other business transformation efforts.” **RISKS RELATED TO OUR BUSINESSES** We are exposed to the risk of cyber incidents, which can result from deliberate attacks or unintentional events, in the normal course of business. We use ~~web- enabled and other~~ integrated information and technology systems to manage our business ; **and** deliver products and services to customers. In particular, the 2022 launch of **our cloud solution-DS Core, a-our cloud platform** that integrates digital dentistry workflows across devices, **has and the 2024 launch of Primescan 2, a cloud-native intraoral scanner, have** introduced new potential vulnerabilities to cyber attacks **within our service delivery model.** **The breadth and complexity of our information and technology systems have increased and we** expect that ~~the~~ **they** breadth and complexity of our information and technology systems will **continue to** increase as we expand the services enabled by ~~the~~ **DS Core platform** and further develop our ERP systems and product offerings to utilize artificial intelligence (“ AI ”) and analytics. As a result, we will increasingly be exposed to risks inherent in the development, integration and operation of the

evolving information and technology supporting our product platforms, as well as our own internal infrastructure, including: • security breaches, viruses, cyberattacks, ransomware or other malware or other failures, **cyber incidents** or malfunctions; • disruption, impairment or failure of data centers or hardware, telecommunications facilities or other infrastructure **platforms**, **including due to natural disasters**; • failures during the process of upgrading or replacing software, databases or components **contained in the information and technology infrastructure**; • the compromise or unauthorized disclosure of sensitive or **personal, proprietary or intellectual property** information related to our business and customers; • excessive costs, excessive delays or other deficiencies in systems development and deployment; and • an unintentional event that involves a third-party gaining unauthorized access to our systems or proprietary information. We also utilize systems, applications and data storage provided and maintained by third parties, including those delivered through cloud-based solutions. Any disruptions to or deterioration of our distribution partners' or service providers' information and technology infrastructures could pose a threat to our operations and harm our business. ~~We continue to experience an increase in cyber threats focused on gaining unauthorized access to our information and technology infrastructure for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Although we take measures designed to protect such information from unauthorized access, use or disclosure, our and our service providers' infrastructures and storage applications may be impaired due to unauthorized access by hackers, ransomware, phishing attacks, human error, malfeasance, natural disasters, telecommunications and electrical failures and other disruptions. Cyber threats are rapidly evolving and are becoming increasingly sophisticated, with an increase in the frequency of cyber incidents. Like other large, global companies, during the normal course of business, we have experienced and expect to continue to experience cyber threats, attacks and other attempts to compromise our information system systems, although with such attacks and threats rapidly increasing in both sophistication and frequency. However,~~ none, to our knowledge, ~~has have~~ had a material adverse effect on our business, financial condition or results of operations to date. ~~Anyone who circumvents our security measures could misappropriate proprietary information, including information regarding us, our employees, our service providers and / or our customers, or cause interruptions in our operations. We cannot provide assurances that, although past cybersecurity incidents have not had a material effect on our business or operations to date and despite our efforts to ensure the integrity of our systems and the measures that we or our service providers take to anticipate, detect, avoid or mitigate such threats, a future cyberattack would not result in material harm to us or our business and results of operations. For example, certain techniques used to obtain unauthorized access, introduce malicious software, disable or degrade service, or sabotage systems may be designed to remain dormant until a triggering event occurs and we may be unable to anticipate these techniques or implement adequate preventive measures since techniques change frequently or are not recognized until launched, and because cyberattacks can originate from a wide variety of sources. These data breaches and any unauthorized access or disclosure of our information could compromise intellectual property and expose sensitive business information. Our policies, required employee training (including that which relates to phishing prevention training), procedures and technical safeguards may be insufficient to prevent or detect improper access to confidential, proprietary or sensitive data, including personal data. Cyberattacks could also cause us to incur significant costs to recover from breaches, disrupt key business operations and divert attention of management and key information technology resources. We also face the ongoing challenge of managing controlling access controls to our information and technology infrastructure. We have experienced various types of cyber incidents in the past and as the result of such incidents, we have implemented new controls, governance, technical protections and other procedures as a result. If we do not successfully manage these access controls, it could expose us to the risk of security breaches or disruptions. Any Although past cybersecurity incidents have not had a material effect on our business or operations, and although we and our service providers take efforts to ensure the integrity of our systems and anticipate, detect, avoid or mitigate such security breaches or disruptions threats, we cannot provide assurances that a future cyberattack could would not compromise the security or integrity of our networks or result in the loss, misappropriation, and /..... harm and significant remediation costs and experience material harm to our business and financial results if we experience cyber incidents in the future. AI-based platforms and tools are increasingly being used in the consumer health industries, and our use of this technology, as well as its..... have a material adverse effect on our operations and reputation as well as the operations of any of our business partners. The materialization of any of these risks may impede the utilization of the Company's product offerings, the processing of data and the day-to-day management of our business and could result in the corruption, loss or unauthorized disclosure of proprietary, confidential or other data. Disaster recovery plans, where in place, might not adequately protect us in the event of a system failure. Further, we currently do not have excess or standby computer processing or network capacity everywhere in the world to avoid disruption in the receipt, processing and delivery of data in the event of a system failure. Despite any precautions we take, damage from natural disasters fire, floods, hurricanes, power loss, telecommunications failures, computer viruses, break-ins, human error or similar events at our various computer facilities could result in interruptions in the flow of data to our servers, although we have not yet experienced such an interruption. this technology, as well as its use by our business partners with access to our confidential information, including trade secrets, may continue to increase and could lead to the unintentional release of such our confidential information, which could negatively impact us, including our ability to realize the benefits of our intellectual property. Additionally, the advancement of AI and large language models has given rise to additional vulnerabilities and potential entry points for cyber threats. With generative AI tools, threat actors may have additional tools to automate breaches or persistent attacks, evade detection, or generate sophisticated phishing emails, or impersonate employees or senior management. Our use of AI in our products and processes and the use of AI by our business partners may lead to novel and urgent cybersecurity, legal and regulatory risks, which could have a material adverse effect on our operations and. Additionally, we seek to maintain insurance coverage for cybersecurity risks associated with cybersecurity, but such insurance has become increasingly difficult to secure and, in some cases, policies may not provide adequate coverage for possible losses. Further, as cybersecurity risks evolve, such insurance may not be available to us on commercially reasonable terms, or at all. Uninsured~~

losses or operational losses that result from large deductible payments under commercial insurance coverage might have an adverse impact on our business operations, and our financial position or results of operations. Any of the foregoing incidents could also subject us to liability, expose us to significant expense, or cause significant harm to our reputation and result in lost revenue. While we have invested and continue to invest in information technology risk management and disaster recovery plans, these measures cannot fully insulate us from cyber incidents, technology disruptions or data loss and the resulting adverse effect on our operations and financial results. We collect and process personally identifiable information (“ PII ”) and other data as part of our business processes and activities. This data is subject to a variety of U. S. and foreign laws and regulations, including oversight by various regulatory or other governmental bodies. Many foreign countries and governmental bodies have laws and regulations concerning the collection and use of PI and other data obtained from their residents or by businesses operating within their jurisdictions. The EU General Data Protection Regulation (“ GDPR ”), for example, imposes stringent data protection requirements and provides significant penalties for noncompliance. Fines for noncompliance can amount to up to € 20 million or 4 % of the total worldwide annual sales from the preceding financial year (whichever is higher) and may be imposed in conjunction with the exercise of the authority’s investigatory and corrective powers. The GDPR’s extraterritorial scope makes it applicable to our U. S.- based legal entities whenever our business activities process the personal data of EU residents. Privacy laws, rules and regulations are also rapidly developing in other regions, including China, Brazil and South Korea, and the United States. In the United States, the federal Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (collectively, “ HIPAA ”) impose certain requirements on covered entities and their business associates to protect the privacy and security of protected health information (“ PHI ”) and to provide notification in the event of a breach of PHI. The U. S. Department of Health and Human Services Office for Civil Rights (“ OCR ”), which is responsible for enforcing HIPAA, also may enter into resolution agreements requiring the payment of civil money penalties and / or the establishment of corrective action plans to address violations of HIPAA. Pursuant to HIPAA, OCR has adopted privacy regulations to govern the use and disclosure of PHI and data security regulations that require the implementation of safeguards to protect electronic PHI. Our Company, through its various subsidiaries, functions as both a covered entity and a business associate under HIPAA. Where necessary, we have segregated our data to ensure that PHI is handled in accordance with HIPAA requirements. We believe that we have implemented appropriate policies and procedures and security measures necessary to comply with HIPAA. However, despite our compliance efforts, we may suffer a serious breach of PHI or be subject to a cyberattack that compromises the PHI that we maintain. Additionally, federal and state privacy and security-related laws may be more restrictive than HIPAA and could impose additional penalties. For example, the Federal Trade Commission uses its consumer protection authority to initiate enforcement actions in response to alleged privacy violations and data breaches. The California Consumer Privacy Act (“ CCPA ”) created additional data privacy obligations for covered companies and a private right of action with statutory damages for certain data breaches. In addition, the California Privacy Rights Act further expanded the CCPA to provide even greater rights to California consumers with respect to their data. Other states have followed California by implementing data privacy laws, including, but not limited to, Colorado, Connecticut, Utah, Virginia, and Washington. If we suffer a serious breach of personal data, we may be subject to breach notification requirements, government investigations, media inquiries, civil and criminal fines and penalties, litigation, and negative public perception, and we may be required to expend substantial financial and personnel resources. Any liability from failing to comply with applicable privacy and data protection laws could adversely affect our operations and our financial condition. These varying laws, rules, regulations and industry standards impact our businesses to the extent we rely on the use of personal data, including PHI, and create significant compliance challenges. In addition, certain privacy and data protection laws may apply to us indirectly through our customers, manufacturers, suppliers or other third- party partners. For example, non-compliance with applicable laws or regulations by a third- party partner that is processing personal data on our behalf may be deemed to be non-compliance or a failure to conduct proper due diligence. Any inability, or perceived inability, to adequately address privacy and data protection concerns, even if unfounded, or to comply with applicable laws, regulations, policies, industry standards, contractual obligations, or other legal obligations (including at newly acquired companies) could result in additional cost and liability to us or our officers, damage our reputation, inhibit sales, and otherwise adversely affect our business. Moreover, global regulation related to the provision of services on the Internet is increasing, as federal, state and foreign governments continue to adopt new laws and regulations addressing data privacy and the collection, processing, storage and use of personal information. Such laws and regulations are subject to new and differing interpretations and may be inconsistent among jurisdictions. These and other requirements could reduce demand for our products or services or restrict our ability to store and process data or, in some cases, impact our ability to offer future digital dentistry products and services in certain locations or our ability to deploy our solutions globally. The costs of compliance with and other burdens imposed by these types of laws, regulations and standards may limit the use and adoption of our products or services, reduce overall demand for our products or services, lead to significant fines, penalties or liabilities for noncompliance, any of which could harm our business. The importance of privacy laws, rules and regulations specifically for the healthcare and medical device industry is constantly growing, as personal data has become an integral part of doing business in our sector, and the legal standards are evolving and becoming more complex worldwide. For instance, the GDPR, applicable as of 2018 and still one of the strictest and most comprehensive privacy laws in the world, is being continuously enforced, and fines are now increasingly being levied on businesses. Fines for noncompliance with the GDPR can amount to up to € 20 million or 4 % of the total worldwide annual sales from the preceding financial year (whichever is higher) and may be imposed in conjunction with the exercise of the authority’s investigatory and corrective powers. The GDPR’s extraterritorial scope makes it applicable to our U. S.- based legal entities whenever our business activities, systems and products process the personal data of EU residents. Additionally, privacy

laws, rules and regulations are also rapidly developing in other regions, including China, Brazil and South Korea, and is expanding through the United States, state by state (e. g., California, Virginia, Colorado, Connecticut, and Utah), in parallel with federal privacy laws protecting sensitive health information. These varying laws, rules, regulations and industry standards impact our businesses to the extent we rely on the use of personal data and create significant compliance challenges while maintaining our global reach. In addition, certain privacy and data protection laws may apply to us indirectly through our customers, manufacturers, suppliers or other third-party partners. For example, non-compliance with applicable laws or regulations by a third-party partner that is processing personal data on our behalf may be deemed non-compliance by us or a failure by us to conduct proper due diligence on the third party. In addition, the legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain including, especially in the areas of intellectual property, cybersecurity, and privacy and data protection. For example, there is uncertainty around the validity and enforceability of intellectual property rights related to the use, development, and deployment of AI by us and by our business partners. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant operational costs and may limit the ability of the Company and our business partners to develop, deploy or use AI technologies. Failure to appropriately respond to this evolving landscape may result in legal liability, regulatory action, or brand and reputational harm. New and more stringent multinational, national and state technology legislation and regulations may be adopted in 2024-2025 and beyond. We cannot predict all the scope of jurisdictions in which new legislation, regulation or enforcement might arise, the scope of such legislation jurisdictions that may be involved, regulation and enforcement, or the potential impact to our business and operations of any such changes. Failure to comply with U. S. and international technology laws and regulations could result in government enforcement actions (which could include substantial civil and / or criminal penalties and injunctive relief), private litigation and / or adverse publicity and could have a material adverse impact on our business, financial condition or results of operations. Although we currently maintain liability insurance intended to cover cyber and certain other privacy and security breach-related claims, we cannot ensure that our insurance coverage will be adequate to cover liabilities arising out of claims asserted against us in the future if the outcomes of such claims are unfavorable to us. Liabilities in excess of our insurance coverage, including coverage for cyber liability and certain other privacy and security breach-related claims, could have a material adverse effect on our business, financial condition, results of operations, cash flows and the trading price of our securities. The worldwide markets for dental and continence care products are highly competitive and are subject to rapid and significant technological disruption through new product introductions, changes in consumer preferences, and evolving industry standards and best practices. Our patent portfolio continues to change with patents expiring through the normal course of their life. There can be no assurance that our products will not lose their competitive advantage or become noncompetitive or obsolete as a result of such factors, or that we will be able to generate any economic return on our investment in product development. If product demand or sales effectiveness decreases, or if our newly introduced products are not accepted by our customers, our revenue and profit could be negatively impacted. Important factors that could cause demand for our products to decrease include changes in: • business conditions, including downturns in the dental industry, regional economies, and the overall economy; • the level of customers' inventories; • evolving industry practices; • competitive and pricing pressures, including actions taken or new products introduced by competitors; and • customer product needs and preferences and customer / patient lifecycle ; and • patient reimbursement trends which could lead to a drop in patient volumes at our customers' dental practices. If we fail to innovate existing technologies or develop new technologies through our research and development process consistent with changing consumer preferences and security requirements or fail to differentiate our products from relative to our competition, our technology or products may become obsolete and cause us to lose market share and revenue. We While we have identified the development of new technologies and products as an important part of our growth strategy -, There there is no assurance that entirely new technology, products or approaches to dental treatment or competitors' new products will not be introduced that could render our products obsolete, and there is no assurance that capital allocated to R & D will yield expected benefits. Additionally, the rapid pace of technological advancements may accelerate amortization faster than we anticipated or impair investments in our software technology, which could negatively impact our results. We seek to maintain our reputation for delivering innovative and effective solutions to advance patient care and deliver better, safer, and faster dentistry and continence care under a strong portfolio of world-class brands. Successful promotion of our brand depends on multiple factors, including our marketing efforts and our ability to deliver a superior customer experience, develop innovative products, and successfully differentiate our offerings from those of our competitors. Additionally, the strength of our brand relies on continued effective use of our distribution network and customer service platforms. The promotion of our brand requires us to make substantial expenditures, including recent continued investments in enhancing customer experience -, and we anticipate the need for such expenditures to continue. Our brand promotion activities may not be successful in maintaining or increasing our current level of revenue or yielding increased revenue. If we do not successfully position our brand and reputation as an industry leader, our business and operating results may be adversely affected. Additionally, our brand depends on our reputation for offering high- quality solutions meeting the highest of safety standards. A serious breach of our To safeguard that reputation, we have adopted rigorous quality assurance and -or quality control procedures which are designed to ensure the safety of our products, including incremental investments in improved quality control during the course of 2023. A serious breach of our quality assurance or quality control procedures, deterioration of our quality image, impairment of our customer or consumer relationships or failure to adequately protect the relevance of our brands may lead to litigation, customers purchasing from our competitors, or consumers purchasing other brands or private label items not manufactured by us, or regulatory enforcement action, any of which could have a material negative impact on our business, financial condition or results of operations. We operate in approximately more than 150 countries and our suppliers' manufacturing facilities are located in multiple locations around the world. Potential events such as extreme weather, natural disasters, regional epidemics or global pandemics, worker strikes and social and political

actions, such as trade wars, regional wars or conflicts or other events beyond our control, could impact our ongoing business operations, including ~~potential~~ **due to disruptions at** critical third- party ~~vendor~~ **vendors** ~~disruptions or failure to adhere to contractual obligations affecting our supply chain and manufacturing needs~~ or the loss of critical information technology and telecommunications systems. Although we maintain multiple manufacturing facilities, a large number of the products manufactured by us are manufactured in facilities that are the sole source of such products. As there are a limited number of alternative ~~third- party~~ **suppliers** for these products, any disruption at a particular Company manufacturing facility could lead to delays ~~;~~ **and** increased expenses ~~;~~ and may damage our business and results of operations. If our incident response, disaster recovery and business continuity plans do not resolve these issues in an effective and timely manner, such events could result in an interruption in our operations and could cause material negative impacts ~~to~~ **on our business, financial condition** ~~our~~ **or results** ~~product availability and sales, the efficiency of our operations and our financial results~~. Additionally, a significant portion of our injectable anesthetic products, orthodontic products, certain dental cutting instruments, catheters, nickel titanium products and certain other products and raw materials are purchased from a limited number of suppliers and in certain cases single source suppliers pursuant to agreements that are subject to periodic renewal, some of which may also compete with us. As there are a limited number of suppliers for these products, there can be no assurance that we will be able to obtain an adequate supply of these products and raw materials in the future **at acceptable prices**. Any delays in delivery of or shortages in these products could interrupt and delay manufacturing of our products and result in the cancellation of orders ~~for these products~~. In addition, these suppliers could discontinue the manufacture or supply of these products to us ~~at any time~~ or supply products to competitors. We may not be able to identify and integrate alternative sources of supply in a timely fashion ~~;~~ or at all. Any transition to alternate suppliers may result in delays in shipment ~~and~~ **increased** ~~increase~~ expenses and ~~may~~ limit our ability to deliver products to customers ~~;~~ **We continue to generate a substantial portion of our revenue through a limited number of distributors that provide important sales, distribution and service support to the end- user customers. Together, our two largest distributors, Patterson and Henry Schein, accounted for approximately 21 % of our annual revenue for the year ended December 31, 2023, and it is anticipated that they will continue to be the largest distribution contributors to our revenue through 2024. We may be unable to execute our key strategic activities and investments due to operation** ~~operational~~ **disruptions** impacting our distributors or the competing priorities of our distribution partners ~~;~~ which may introduce additional ~~competing private label, generic, or low- cost~~ products that compete with our products at lower price points. If these competing products capture significant market share or result in a decrease in market prices overall, ~~this~~ **there could be negative impacts on our results of operations and financial condition. We generate a substantial portion of our revenue through a limited number of distributors that provide important support to end- users. Together, our two largest distributors, Patterson Companies, Inc. (“ Patterson ”) and Henry Schein, Inc. (“ Henry Schein ”), accounted for approximately 13 % of our annual revenue for the year ended December 31, 2024. In July 2024, we delivered a one- year notice of non- renewal to Patterson in connection with its non- exclusive distribution agreements for the distribution of dental equipment in the United States and Canada. It is anticipated that Patterson will continue to be one of our two largest distributors as a percentage of our global revenue during the one- year notice period. We intend to engage in discussions for new distribution agreements with Patterson. However, failure to successfully renegotiate the distribution agreements or secure new agreements with another distributor could have a negative impact** ~~material adverse effect~~ **on our business, operating results of operations and financial condition. We have not incurred any charges against earnings in 2024 related to non- renewal of the distribution agreements.** Additionally, some parts of the dental market ~~continue~~ **continues** to be impacted by price competition ~~;~~ that is driven in part by the consolidation of dental practices, the growing significance of DSOs, innovation ~~and product advancements~~ ~~;~~ and ~~the price sensitivity of end- user customers~~ **price sensitivity**. There can be no assurance that our distribution partners will purchase any ~~specified~~ minimum quantity of products from us or that they will continue to purchase any products at all. If Patterson or Henry Schein ceases to purchase a significant volume of products from us, or if changes in our promotional strategies and investments result in changes in our distributor relationships, it could have a material adverse effect on our results of operations and financial condition ~~;~~ **In addition, changes in the capital structure or ownership of distributors could result in changes to our relationship, including shifts in strategies related to inventory management, customer service and servicing the installed base of Dentsply Sirona products. Changes to agreements with distributors, including expiration of existing agreements, could result in a reduction in the amount of inventory ordinarily held in the absence of contractual minimum inventory requirements.** We rely in part on our distributor and customer relationships and predictions of distributor and customer inventory levels in projecting future demand levels and financial results. These inventory levels may fluctuate, and may differ from our predictions, resulting in our projections of future results being different than expected. These changes may be influenced by changing relationships with distributors and customers, economic conditions ~~;~~ and customer preference for particular products. There can be no assurance that distributors and customers will maintain levels of inventory in accordance with our predictions or past history ~~;~~ or that the timing of customers’ inventory ~~changes~~ **build- up or liquidation** will be in accordance with our expectations ~~or historical experience~~. Additionally, we periodically upgrade or replace our various software systems, including our customer relationship management systems. If we encounter unforeseen problems with new systems or in migrating away from our existing applications and systems, our operations and our ability to manage our business could be ~~negatively impacted~~. Any disruptions to our distributors’ operations or systems may result in delays in orders and shipments ~~;~~ and ~~may~~ prevent our products from being timely delivered to the market. We ~~utilize and~~ intend to continue utilizing acquisitions and ~~;~~ ~~dispositions of assets and businesses~~, and strategic investments as a part of our strategy **for growth and to improve financial results. We have made, and may continue to make in the future, acquisitions to enhance our business and product portfolio, which require us to invest significant resources to integrate the businesses we acquire. We also periodically evaluate our businesses and assets for potential disposition as a key part of our strategy, including the previously disclosed evaluation of strategic alternatives for our Wellspect Healthcare business. The success of each**

acquisition or divestiture depends in part on our ability to realize opportunities and manage risks, including challenges executing transactions, higher operating expenses, litigation, adverse effects on existing business relationships with suppliers and customers, and the potential loss of key employees, customers, distributors, vendors, and other business partners. The process of continuing to evaluate acquisitions, divestitures or strategic investments may be costly, time-consuming and complex, including requiring management to devote significant time and attention to these types of transactions that may distract our management and disrupt our ongoing business operations or relationships. We may incur significant legal, accounting and advisory fees and other expenses, some of which may be incurred regardless of whether we successfully enter into a transaction. We may not achieve expected returns and benefits in connection with acquisitions this strategy as a result of various factors, including integration and collaboration challenges, such as those relating to personnel and technology. In addition, and we may not achieve the full financial results consistent with revenue growth expectations and cost synergies anticipated to result from related integration activities. Acquisitions, dispositions and strategic investments may distract our management's time and attention and disrupt our ongoing business operations or relationships with customers, employees, suppliers or other parties. We continue to evaluate the potential disposition of assets and businesses that may no longer help us achieve our strategic objectives, and to view acquisitions as a key part of our growth strategy. After reaching an agreement with a seller for the acquisition or buyer for the disposition of assets or a business, the transaction may remain subject to necessary regulatory and governmental approvals and on acceptable terms as well as the satisfaction of pre-closing conditions, which may prevent us from completing the a given transaction in a timely manner, or at all. Acquisitions may require us to incur debt, assume contingent liabilities and / or additional risks, or create additional expenses to consummate the transaction, any of which might adversely affect our financial results. When we pursue the divestiture of decide to sell assets or a business, we may encounter difficulty in finding buyers or executing alternative exit strategies on acceptable terms in a timely manner, which could delay the accomplishment of our strategic objectives. Alternatively, we may dispose of a business at a valuation or on terms that are less favorable than we had anticipated, or with the exclusion of select assets. Dispositions may also involve continued involvement in a divested business, such as through continuing equity ownership, transition service agreements, guarantees, indemnities or other current or contingent financial obligations. Under these arrangements, the performance of the acquired or divested business, or other conditions outside our control, could affect our future financial results. Additionally, If we are not successful in setting forth a new strategic vision for Wellspect, or if we make acquisitions our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and they the value of may incur debt, assume contingent liabilities and / or our securities may be additional risks, or create additional expenses, any of which might adversely impacted affect our financial results. Any financing that we might need for acquisitions may only be available on terms that restrict our business or that impose additional costs that reduce our operating results. In order to improve performance operate more efficiently and control costs drive value creation, we implemented a restructuring plan during the course of 2023-2024 (the "2024 Plan"). In connection with the 2024 Plan, we anticipate a net reduction in our global workforce of approximately 2 % to 4 %. The proposed changes are subject to co-determination processes with employee representative groups in countries where required. Actions taken under the 2024 Plan will seek to further streamline our operations and global footprint, as well as improve alignment of our cost structure with strategic growth objectives. In addition, we made organizational restructuring changes during 2023 (the "2023 Plan") in order to simplify structure, enhance profitability, improve operational performance and drive growth. These The 2023 Plan plans included implementation of a new operating model with five global business units designed to drive enterprise integration and align the our product portfolio with our growth strategy, commencement of our central functions and infrastructure optimization to support efficiency of the overall organization, and other initiatives aimed at delivering cost savings to fund critical investments in 2023 and to position the Company for sustainable future growth. We The failure to execute such initiatives as part of our business strategy could minimize the expected benefits to the organization resulting in potential adverse impacts to ongoing operations and cost overruns. As part of these initiatives, we are also in the process of implementing a new global ERP system, which will upgrade and standardize our existing information systems. In Beginning in 2023 and continuing through 2024, we started to make made capital investments in this system, which has resulted in significant costs and uses of cash, and which will that are expected to continue to result in the additional costs and uses of cash in future periods. Implementation is expected to take several years to complete, and Cost cost overruns or any disruptions, delays or complications in the course of making this transition could lead to higher than anticipated capital investments and related costs, distract from the operation of our core business, or result in failures to produce financial information accurately and timely and. Additionally, any delay or other failure to achieve our implementation goals may adversely impact our financial results. The failure to either deliver the application on time or anticipate the necessary readiness and training needs could lead to business disruption disruptions and loss. The quarterly timing of sales may also be impacted as distributors adjust their buying patterns and inventory levels in anticipation of potential business disruptions related to the implementation of our new ERP system. Failure or abandonment of any part of the ERP system could result in a write-off of part or all of the costs that have been capitalized on the project. Additionally, our ability to achieve the benefits from any of our strategic initiatives within the expected timeframe time frame is subject to many estimates, assumptions, and other factors that we may not be able to control. We may also incur charges related to restructuring plans that are higher than anticipated, which would reduce our profitability in the periods such charges are incurred. Due to the complexities inherent in implementing these types of cost reduction and restructuring activities, and the timing of strategic investments, we may fail to realize expected efficiencies and benefits, such as the goals for net sales growth or operating margins, or may experience a delay in realizing such efficiencies and benefits, and our operations and business could be disrupted. Company management may be required to divert their focus to managing these disruptions, and implementation may require the agreement of third parties, such as labor unions or works councils. Risks associated with these actions and other

workforce management issues include delays in implementation of anticipated workforce reductions, additional unexpected costs, changes in restructuring plans that **modify** increase or decrease the number of employees affected, negative **impact impacts** on our relationship with labor unions or works councils, adverse effects on employee morale, and the failure to meet operational targets due to the loss of employees, any of which may impair our ability to achieve anticipated cost reductions or may otherwise harm our business, and could have a material adverse effect on our sales growth and other results of operations, cash flows or financial condition, or competitive position. **We have acquired other companies and intangible assets and may not realize all the economic benefit from those acquisitions, which could cause an impairment of goodwill or intangibles. We review amortizable intangible assets for impairment when events indicate the carrying value may not be recoverable**. We test goodwill and indefinite-lived intangibles for impairment at least annually. The valuation models used to determine the fair value of goodwill or indefinite-lived intangible assets are dependent upon various assumptions and reflect management's best estimates. ~~We have acquired other companies and intangible assets and may not realize all the economic benefit from those acquisitions, which could cause an impairment of goodwill or intangibles.~~ The goodwill and indefinite-lived intangible asset impairment analyses are sensitive to changes in key assumptions used, such as discount rates, revenue growth rates, perpetual revenue growth rates, ~~royalty rates, and~~ operating margin percentages, **and net working capital assumptions** of the business as well as current market conditions affecting the dental and medical device industries ~~in both the United States and globally~~. Given the uncertainty in the marketplace and other factors affecting management's assumptions ~~underlying~~, **there is a risk of future impairment charges if there is a decline in the fair value of the reporting units** ~~our~~ or discounted cash flow model ~~indefinite-lived intangible assets as a result of~~, among the other things, financial results lower than forecasts, adverse ~~changes in valuation~~ assumptions and projections, a decline in equity valuations, increases in interest rates, or changes in ~~the used-~~ use of intangible assets. There can be no assurance that our future asset impairment testing will not result in a ~~the analyses may deviate materially~~ material charge to earnings. In the quarter ended March 31, 2024, we identified indicators of a more likely than not impairment related to certain indefinite-lived imaging product trade names within the Connected Technology Solutions segment. The decline in fair value of these indefinite-lived trade names was driven by declines in volumes during the three months ended March 31, 2024, which was due in part to a loss in market share from ~~future assumptions~~ competitive pricing pressures, as well as unfavorable economic conditions in certain markets. **These factors contributed to a reduction in forecasted revenues in the near term. The trade names were evaluated for impairment using** ~~and an income approach~~ projections and our current estimates could vary significantly in the future, which may ~~specifically a relief from royalty method.~~ As a result in, we recorded an additional goodwill or indefinite-lived intangible asset impairment charge at that time of \$ 6 million for the three months ended March 31, 2024. In preparing the financial statements for the quarter ended September 30, ~~2023-2024~~, the Company identified indicators of a more likely than not impairment ~~related for to two of its Connected Technology reporting units, Orthodontic Aligner Solutions and Implant & Prosthetic Solutions, which together comprise all of the Orthodontic and Implant Solutions segment. As a result, the Company recorded pre-tax goodwill impairment charges as of September 30, 2024 of \$ 145 million for the Orthodontic Aligner Solutions reporting unit, which comprises all and \$ 359 million for the Connected Technology Implant & Prosthetic Solutions reporting unit, both within the Orthodontic and Implant Solutions segment. The impairment charge related to the Orthodontic Aligner Solutions reporting unit resulted in a full write-off of the remaining goodwill balance for this reporting unit. In the quarter ended December 31, 2024, the Company identified indicators of a more likely than not impairment for its Implant & Prosthetic Solutions reporting unit within the Orthodontic and Implant Solutions segment. The decline in fair value of this reporting unit was driven by a weaker trend in sales volumes, particularly in North America, increased competition from lower-priced alternatives impacting global markets, and adverse macroeconomic pressures impacting demand for elective dental procedures and premium implant solutions. These factors contributed to reduced forecasted revenues, lower operating margins, and reduced expectations for future cash flows.~~ As a result, the Company recorded a pre-tax goodwill impairment charge as of September 30 ~~December 31~~, 2023-2024, related to the Connected Technology Solutions reporting unit of \$ 291-269 million, resulting in a full write-off of the remaining goodwill balance for the **Implant & Prosthetic** Connected Technology Solutions segment. Additionally, in conjunction with the goodwill impairment test in the quarter ended September 30, 2023, the Company tested the long-lived intangible assets related to the businesses within the Connected Technology Solutions reporting unit within the **Connected Technology Orthodontic and Implant** Solutions segment for impairment. ~~The~~ **For further information, see Note 11, Goodwill and Intangible Assets, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10-K.** Additionally, in the quarter ended **December 31, 2024**, the Company also identified an indicator ~~indicators~~ of more likely than not ~~impairment impairments~~ for the certain indefinite-lived intangible assets including trade names and trademarks within the **Connected Technology Solutions segment, and certain trade names within the Implants- Implant & Prosthetics- Prosthetic Solutions** reporting unit within the Orthodontic and Implant Solutions segment, and determined certain tradenames. **The decline in fair value of the trade names and trademarks were impaired was driven by weakened demand for our premium equipment and implant products, competitive pricing pressures, and a sustained higher cost of capital, which are contributing to reduced forecasted revenues.** As a result, the Company recorded indefinite-lived intangible asset impairment charges of \$ **14-82** million and \$ **2-1** million for the Connected Technology Solutions and Orthodontic and Implant Solutions segments, respectively, for the three months ended ~~September 30~~ **December 31**, 2023-2024. **For further information, see Note 11, Goodwill and Intangible Assets, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10-K.** The remaining goodwill balance of the **Implant & Prosthetic Solutions** reporting unit was \$ 503 million as of **December 31, 2024**, and the carrying values of indefinite-lived intangible assets ~~impaired with impairments~~ in the ~~third-fourth~~ quarter of 2023 were \$ **215-76** million and \$ **23-149** million for the **Implant & Prosthetic Solutions and** Connected Technology Solutions reporting units and Orthodontic and Implant Solutions segments, respectively, as of **December 31, 2023-2024**. As the fair

values of the Implant & Prosthetic Solutions reporting unit and the indefinite-lived assets within the Implant & Prosthetic Solutions and Connected Technology Solutions reporting units, respectively, continue to approximate carrying value as of these December 31, 2024, any further decline in key assumptions could result in future additional impairment. At December 31, 2024, we have \$ 337 million of indefinite-lived intangible assets continues to approximate carrying value as of December 31, 2023, any further decline in key assumptions could result in additional impairments in future periods. As of December 31, 2023, the Company considered qualitative and quantitative factors to determine whether any events or changes in circumstances had changed the likelihood that the goodwill or indefinite-lived intangible assets may have become more likely than not impaired during the fourth quarter and concluded there were no such indicators. At December 31, 2023, the Company has \$ 452-1, 597 million of indefinite-lived intangible assets and \$ 2. 4 billion of goodwill recorded on its ~~our~~ balance sheet. Our financial results may be adversely impacted if third parties infringe upon our intellectual property rights or misappropriate our technologies and trademarks ~~for their own businesses~~. To protect our rights to our intellectual property, we rely on a combination of patent and trademark law, trade secret protection, confidentiality agreements and contractual arrangements with our employees, strategic partners, ~~and others~~. We cannot assure you that any of our patents, ~~any of the patents of which we are a licensee~~ license or any patents which may be issued to us or which we may receive or license in the future, will provide us with a competitive advantage or afford us protection against infringement ~~by others~~, or that the patents will not be successfully challenged or circumvented by third parties, ~~including our competitors~~. The protective steps that we have taken may be inadequate to **detect, protect against or** deter misappropriation of our proprietary information. We may be unable to detect or protect against the unauthorized use or misappropriation of, or take appropriate steps to enforce, our intellectual property rights. Effective patent, trademark and trade secret protection may not be available in every country in which we will offer, ~~or intend to offer~~, our products. **In addition, there is a risk of employees inadvertently inputting trade secret information into AI technologies, thereby enabling third parties to access such information**. Any failure to adequately protect our intellectual property rights could devalue our proprietary content and impair our ability to compete effectively. Further, defending **or enforcing** our intellectual property rights could result in the expenditure of significant financial and managerial resources. Litigation may be necessary to assert claims against ~~other others parties~~, enforce patents owned by or licensed to us ~~from another party~~, protect our trade secrets or know-how, or determine the enforceability, scope, and validity of our proprietary rights. An adverse determination in **such** proceedings ~~of this type~~ could subject us to significant liabilities, allow our competitors to market competitive products without obtaining a license from us, prohibit us from marketing our products or require us to seek licenses from third parties ~~that may not be available on commercially reasonable terms, if at all~~. If we cannot obtain such licenses, we may be restricted or prevented from commercializing our products. If we become involved in litigation, we may incur substantial expense, and the proceedings may divert the attention of key personnel, even if we ultimately prevail. Our success will depend in part on our ability to obtain patents for technology in our products and defend infringement on our patents by third parties that relate to our products, technologies, ~~and processes~~, both in the United States and in other countries. Risks and uncertainties that we face with respect to our patents and patent applications include the following: • the pending patent applications ~~that we have filed, or to which we have exclusive rights~~, may not result in issued patents or may take longer than we expect to result in issued patents; • the allowed claims of any patents that are issued may not provide meaningful protection; • other companies may challenge patents licensed or issued to us; • disputes may arise regarding inventions and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us and our respective licensors; and • other companies may design around the technologies patented by us. From time to time, third parties may claim that one or more of our products or services infringe their intellectual property rights. ~~We analyze and take action in response to such claims on a case-by-case basis~~. Litigation may be necessary to defend against any such claims of infringement of rights owned by third parties that are asserted against us. In addition, it may be necessary to participate in ~~one or more interference~~ proceedings declared by the U. S. Patent and Trademark Office, the European Patent Office or other foreign patent governing authorities, to determine the priority of inventions, which could result in substantial costs. Acquisitions by us of products, technologies or processes, either through acquisitions of businesses or assets, that are found to infringe upon the intellectual property rights of others and the resulting changes to the competitive landscape of the industry could further increase this risk. If we become involved in litigation or interference proceedings, we may incur substantial expense, and the proceedings may divert the attention of key personnel, even if we ultimately prevail. The enforcement, defense and prosecution of intellectual property rights, including the U. S. Patent and Trademark Office's, the European Patent Office's and other foreign patent offices **to determine the priority of inventions, which could result in substantial costs. Acquisitions by us of products, technologies or processes that are found to infringe upon others' interference intellectual property rights could further increase the risk of litigation or other** proceedings, and related costs. **The enforcement legal and administrative proceedings in the United States and elsewhere, defense and prosecution of intellectual property rights** involve complex legal and factual questions. As a result, these proceedings are costly and time-consuming, and their outcome is uncertain. We utilize short and long-term debt markets to obtain capital from time to time. Our continued access to sources of liquidity depends on multiple factors, including global economic conditions, the condition of global credit markets, the availability of sufficient amounts of financing, operating performance, and credit ratings. Macroeconomic impacts, including natural disasters, pandemics, geopolitical conditions or other catastrophic events, may result in significant disruption in the credit markets, which may adversely affect our ability to refinance existing debt or obtain additional financing to support operations or to fund new acquisitions or capital-intensive internal initiatives. Any adverse changes in our credit ratings may result in increased borrowing costs for future long-term debt or short-term borrowing facilities which may in turn limit financing options, including access to the unsecured borrowing market. There is no guarantee that additional debt financing will be available in the future to fund obligations, or that it will be available on commercially reasonable terms, in which case we may need to seek other sources of funding. ~~In addition, the terms~~ **We now have and expect**

to continue to have a significant amount of future debt agreements. Our indebtedness could have important consequences to us including additional the following: • making it more difficult or even impossible for us to satisfy our debt or contractual obligations; • exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under our senior secured credit facilities, are at variable rates of interest; • restrictive-restricting covenants that us from making strategic acquisitions or causing us to make non- strategic divestitures; • requiring us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, which would reduce the funds available for working capital, capital expenditures, investments, acquisitions and other general corporate purposes; • limiting our flexibility in planning for, or reacting to, changes in our business, future business opportunities and the industry in which we operate; • placing us at a competitive disadvantage compared to any of our less leveraged competitors; • increasing our vulnerability to a downturn in our business and both general and industry- specific adverse economic conditions; and • limiting our ability to obtain additional financing, which could worsen if any adverse changes in our credit ratings occur. We have debt securities outstanding of approximately \$ 1. 9-7 billion as of December 31, 2023-2024. We also can incur up to \$ 700 million of indebtedness under the multi- currency revolving credit facility (“ 2023 Credit Facility ”), as discussed below, and may incur significantly more indebtedness in the future. Our credit facilities current debt agreements contain restrictive a number of covenants and financial, including some which require that we maintain certain ratios, which we are required that could limit our ability to engage in activities that may be in our long- term best satisfy. Under the Note Purchase Agreement dated December 11, 2015, we are required to maintain ratios of debt outstanding to total capital not to exceed the ratio of 0. 6 to 1. 0, and operating income excluding depreciation and amortization to interest interests expense of not less than 3. 0 times, in each case, as such terms are defined in the Note Purchase Agreement. Many of our subsequent private outstanding debt agreements have been amended to reflect these covenants. We may need to reduce the amount of our indebtedness outstanding from time to time to comply with the ratios required by such ratios- covenants, though although no assurance can be given that we will be able to do so. Our failure to comply with maintain such ratios or a breach of the those other covenants under our debt agreements outstanding from time to time could result in an event of default under which, if not cured or waived, could result in the applicable agreement acceleration of all of our debt, which could adversely affect our business, earnings and financial condition. Such failure a default may allow the creditors to comply with accelerate the related indebtedness and may result in the acceleration of any other indebtedness. Any future violations of the covenants under our debt agreements may also hurt our reputation and credibility with our stockholders and our debt holders and may compromise our future ability to finance our operations through the public equity or debt markets. Breach of covenants could have additional negative consequences including, but not limited to the following: • increased difficulty to satisfy our obligations with respect to our indebtedness; • requiring us to dedicate significant cash flow from operations to the repayment of principal and interest payments on our indebtedness, which would reduce the funds we have available for other purposes, including working capital, capital expenditures, research and development, dividends, share repurchases and acquisitions; and • reducing our flexibility in planning for or reacting to changes in our business and market conditions. There is no guarantee that we will be able to renew or replace our existing debt agreements as they become due, including debt instruments with principal of \$ 74-128 million maturing in October-December 2024-2025, which. A failure to renew or replace such agreements and instruments would harm our overall liquidity. Our ability to make payments on our indebtedness and contractual obligations, and to fund our operations depends on our future performance and financial results, which, to a certain extent, are subject to general economic, financial, competitive, regulatory and other factors and the interest rate environment that are beyond our control. Although management believes that we have and will continue to have sufficient liquidity, there can be no assurance that our business will generate sufficient cash flow from operations in the future to service our debt, pay our contractual obligations and operate our business. Due to the global nature of our business, movements in foreign exchange rates may impact our consolidated statements of operations, consolidated balance sheets and consolidated statement of cash flows. With approximately two- thirds of our sales located outside the United States, our consolidated net sales are impacted negatively by the strengthening or and positively by the weakening of the U. S. dollar as compared to certain foreign currencies. Additionally, movements in certain foreign exchange rates may impact our results of operations, financial condition, and liquidity since a number of our manufacturing and distribution operations are located outside of the United States. Although we currently use and may in the future use certain financial instruments to attempt to mitigate market fluctuations in foreign exchange rates, there can be no assurance that such measures will be effective, or available through financial markets or that they will not create additional financial obligations for us. We use foreign currency exchange forward contracts to reduce the effects of exchange rate fluctuations, which may limit our potential gains or expose us to losses. Should our counterparties to such transactions or the sponsors of the exchanges through which these transactions are offered fail to honor their obligations due to financial distress or otherwise, we would be exposed to potential losses or the inability to recover anticipated gains from these transactions. We enter into foreign currency exchange forward contracts as economic hedges of trade commitments or anticipated commitments denominated in currencies other than the functional currency to mitigate the effects of changes in currency rates. Although we do not enter into these instruments for trading purposes or speculation, and although our management believes all of these instruments are economically effective for accounting purposes as hedges of underlying physical transactions, these foreign exchange commitments are dependent on timely performance by our counterparties. Their failure to perform could result in us having to close these hedges without the anticipated underlying transaction and could result in losses if foreign currency exchange rates have changed. We enter into interest rate swap agreements from time to time to manage some of our exposure to interest rate volatility. These swap agreements involve risks, such as the risk that counterparties may fail to honor their obligations under these arrangements. In addition, these arrangements may not be effective in reducing our exposure to changes in interest rates. If such events occur, our results of operations may be adversely affected. Most of our cash deposited with banks is not insured and would be subject to the risk of bank failure. Our

total liquidity also depends in part on the availability of funds under our 2023 Credit Facility. The failure of any bank in which we deposit our funds or that is part of our 2023 Credit Facility could reduce the amount of cash we have available for operations and additional investments in our business. RISKS RELATED TO OUR GLOBAL OPERATIONS Approximately two-thirds of our sales are in regions outside the United States. In addition, and we anticipate that sales outside of the United States will continue to increase expand and account for a significant portion of our revenue. Operating internationally is subject to uncertainties, including, but not limited to, those related to, the following: • economic and political instability; • import or export licensing requirements; • additional compliance-related risks; • trade restrictions and tariffs; • product registration requirements; • longer payment cycles; • changes in regulatory requirements and tariffs, including recent restrictions in China on the proportion of certain medical equipment which can be imported; • potentially adverse tax consequences; and • trade policy changes. Changes in or the imposition of tariffs, including the tariffs imposed or proposed by the Trump Administration in early 2025 and retaliatory tariffs imposed or proposed by other countries, could make it significantly more difficult or costly for us to export our products to other countries. In particular, these tariffs currently affect some of the components of our products we import from China and other countries, and we may be required to raise our prices on those products due to these tariffs or share the cost of such tariffs with our customers, which could harm our operating performance. We monitor and evaluate the potential impact of the effective and proposed tariffs as well as other recent changes in foreign trade policy on our supply chain, costs, sales and profitability, and we seek to implement strategies to mitigate such impact, including reviewing sourcing options and working with our vendors and merchants to seek to minimize products coming from China and other countries, both for existing products and for new product development, and we seek to select suppliers in low cost regions where tariff issues are less challenging. These measures could also result in increased costs for goods imported into the United States, supply chain inefficiencies and decreased availability of certain materials with respect to other countries. This in turn could require us to increase prices to our customers, which may reduce demand. If, or, if we are unable to increase prices at a sufficient level to offset tariffs, result in we would be required to lowering lower our margin on products sold. We cannot predict future what additional actions may ultimately be taken by the United States or other governments with respect to tariffs or trade policy or the terms of any renegotiated trade agreements and their impact on relations, what products may be subject to such actions (including subject to United States export control restrictions), our or business what actions may be taken by other countries in retaliation. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers and our suppliers, which in turn could adversely impact our business, financial condition and results of operations. Specifically, the Chinese government has implemented a volume-based procurement process designed to decrease prices for medical devices and other products, which has in the past resulted in, and could in the future result in, reduced margins on covered devices and products, required renegotiation of distributor arrangements, or an incurrence of inventory-related charges. For further information, please see Part I. Item 1, “Business- Regulation.” As a result of such program, which took effect in the first half of 2023, the Company experienced a temporary reduction in net sales of implant products in China, in part due to price reductions, which was offset by higher net sales volumes in the second half of 2023. We cannot predict future impacts of the volume-based procurement program on our business, including any expansion of the program to include additional products within our portfolio. Certain of these risks may be heightened because of changing political climates which may lead to changes in areas such as trade restrictions and tariffs, regulatory requirements and exchange rate fluctuations, which may adversely affect our business and financial performance. For example, due to escalating tensions and the subsequent invasion of Ukraine by Russia, various the United States, other North Atlantic Treaty Organization member states, the EU and other countries and international organizations have imposed sanctions on Russia, including its major financial institutions and certain other businesses and individuals, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People’s Republic, and the so-called Luhansk People’s Republic. Russia also imposed significant currency control measures aimed at restricting the outflow of foreign currency and capital from Russia, imposed various restrictions on transacting with non-Russian parties, banned exports of various products, and imposed other economic and financial restrictions. These include including reducing restrictions on the ability of companies to repatriate or otherwise remit cash from their Russian-based operations to locations outside of Russia. Beginning in September 2024, as a result of further restrictions by European financial institutions on receiving payments from Russia may, our capacity to receive intercompany payments for the delivery of our products into Russia has been partially reduced, which further respond limits our ability to use cash received from sales in kind, and the Russia for our general purposes. The continuation of the conflict may result in additional sanctions being enacted by the United States imposed on Russia and related individuals and entities, with Russia potentially responding in kind other North Atlantic Treaty Organization member states, the EU or other countries. The length, impact, and outcome of this ongoing military conflict is highly unpredictable and could lead to significant market and other disruptions, which, along with the spillover effect of ongoing civil, political, and economic disturbances on surrounding areas, may significantly devalue currencies we utilized by us use or have other adverse impacts, including increased costs of raw materials and inputs, manufacturing or shipping delays or increases in inflation rate, cyberattacks and supply chain challenges. Export controls implemented as part of sanctions could also restrict the sale of equipment or products containing U. S. developed software and technology into Russia. For the year ended December 31, 2023-2024, net sales in Russia and Ukraine were approximately 2 % of our consolidated net sales, and net assets in these countries were \$ 78-64 million. These net assets include \$ 42-39 million of cash and cash equivalents held within Russia as of December 31, 2023-2024, as well as inventory and trade accounts receivable. Due to currency control measures imposed by the A significant escalation or expansion of economic disruption could interrupt our supply chain, broaden inflationary costs, impair our assets located in Russian- Russia government, which include restrictions result in a loss of sales, and have a material adverse effect on the ability of companies to repatriate

or our results of otherwise remit cash from their Russian-based operations to locations outside of Russia, we may be limited in our ability to transfer this cash balance out of Russia without incurring substantial costs, if at all. The recent terrorist attacks by Hamas militants crossing the border from Gaza to Israel in October 2023 and the subsequent military response by the Israeli government in Gaza has resulted in significant unrest and uncertainty within that region. During 2024, including the possibility that escalating state of Israel has also been a target of coordinated missile and drone attacks launched by the Republic of Iran and its proxies. In January 2025, a cease-fire agreement was signed between Hamas and the Israeli government; however, its potential to lead to a long-term peace deal or greater stability remains uncertain. A potential resumption of violence and/or the involvement of other terrorist groups from neighboring or foreign powers in the region could impact our employees and operations in future periods. Additionally, in May 2024, in response to ongoing military actions, the government of Turkey implemented restrictions on the import of goods manufactured within Israel for sale in the Turkish market. Sales of our products made in Israel and sold in Turkey represent approximately 1 % of our global sales of Implant & Prosthetic Solutions reporting unit, but this product category is an area of relatively high potential growth. It is not clear when these restrictions will be lifted or if other countries will institute similar restrictions may further impact our employees and operations. Our The Company's operations in Israel consist of two manufacturing facilities for implants- implant products, with one site in northern Israel and one in southern Israel, which together and combined they employ approximately 300-350 associates. These facilities remain open and continue to operate. We may, however, determine to discontinue production for the safety of our employees, or we could face future production slowdowns or closures interruptions at either location due to the impacts of the war, including having personnel absences as several of our employees were called to active military duty, or due to other resource constraints, such as the inability to source materials for production. For the year ended December 31, 2023-2024, net sales of products manufactured produced at these sites comprised approximately 3 % of our consolidated net sales and 13 % of the net sales attributed to our Orthodontic and Implant Solutions segment. Net assets within Israel totaled \$ 197-180 million as of December 31, 2023-2024, consisting primarily of acquired technology, property, plant and equipment, cash, and inventory, and property, plant and equipment associated with our operations in country. Our operations in Israel have not been materially impacted by the conflict, and consequently, we have not recorded any allowance for doubtful accounts, inventory reserves, or fixed asset impairments through the year ended December 31, 2024. The full impact of these events on economic conditions in these regions Company continues to monitor developments and prepare contingency plans to limit potential disruptions. Additionally, we sell products from across our portfolio to distributors and dental practices within Israel and is its currently unknown neighbors which may face reduced patient traffic and demand for our products in the near term. Net sales for products sold to our customers in Israel comprised approximately 1 % of our consolidated net sales for the year ended December 31, 2024. While Israel does not constitute a material portion of our business, a significant escalation or expansion of the conflict could result in loss of sales and market position, disrupt our supply chain, broaden inflationary costs including energy prices, and have a material adverse effect on our results of operations, cash flows or financial condition. Additionally, other events, such as the outbreak of a global pandemic, including new variants of COVID-19, or other adverse public health developments could materially affect our business in a number of ways, including: • reduced demand for our products in certain regions or our inability to timely meet our customer's orders, • the failure of third parties on which we rely, including our suppliers, customers, contractors, commercial banks, transportation service providers and external business partners, to meet their respective obligations to us, or significant disruptions in their ability to do so, and • uncertainty in the global financial markets access to INTERNAL CONTROLS A description of the capital markets material weaknesses that were remediated during fiscal year 2023 is included under Item 8 of this Form 10-K. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on-in a timely basis. Although in 2022 and 2023, we devoted substantial resources to the remediation efforts to address the identified material weaknesses and in our internal control over financial reporting, some of which resulted in errors in previously issued financial statements. These material weaknesses were all remediated as of December 31, 2023. Although we devote substantial resources to prevent additional material weaknesses from occurring, it cannot be assured that our-the measures we have taken will be sufficient to avoid potential future material weaknesses. Accordingly, there is a reasonable possibility that a reoccurrence of the material weaknesses previously identified or under Item 8. RISKS RELATED TO OUR REGULATORY ENVIRONMENTS As a with the FDA's advertising guidelines may result in the imposition of penalties, enforcement actions, or import bans, and other negative consequences. We are also subject to other federal, state, and local laws, regulations and recommendations relating to safe working conditions, and to laboratory and manufacturing practices. The extent of government regulation that might result from any future legislation or administrative action cannot be accurately predicted, and inadequate employee training for critical compliance and regulatory requirements may result in the failure to adhere to applicable laws, rules, and regulations. Similar to the FDA review process, the EU review process typically requires extended proceedings on-pertaining to the safety and efficacy of new products. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming and may hinder delay or prevent a product's entry into the marketplace. Our products that fall into the category of Class I company with global operations, we are subject to income and taxes, as well as non-income-based taxes around, in the world United States and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable at the time made, the actual outcome could differ materially from the amounts recorded in our financial statements. The Company has significant tax positions in a variety of countries including the United States and Germany. If the U. S. Internal Revenue Service (the "IRS" and such differences may be material). If the IRS or other tax authorities, disagree with the our tax positions we take, we could have additional tax liability, which may and this could have a material impact on our results of

operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, and changes in interpretations of tax laws. Due to economic and political conditions, tax rates in various jurisdictions may be subject to significant change and could materially impact our effective tax rate. Our corporate structure is intended to enhance our operational and financial efficiency and increase our overall profitability. The tax authorities of the countries in which we operate may challenge our methodologies for transfer pricing or change the way in which certain **Certain** transactions are taxed which could materially increase our effective tax rate. In addition, certain governments are considering, and may adopt, tax reform measures that could significantly increase our worldwide tax liabilities. The **Organization** **Organisation** for Economic Co- operation and Development (“ OECD ”) and other government bodies have focused on issues related to the taxation of multi- national corporations, including in the area of “ base erosion and profit shifting, ” where payments are made from affiliates in jurisdictions with high tax rates to affiliates in jurisdictions with lower tax rates. Some of these proposals include a two- pillar approach to global taxation, focusing on global profit allocation and a global minimum tax rate (“ Pillar Two ”). On December 12, 2022, the European Union member states agreed to implement the OECD’ s global corporate minimum tax rate of 15 %, to be **which became** effective as of January 2024. Other countries have made, or are actively considering, changes to their tax laws to adopt certain parts of the OECD’ s proposals. Due to the large scale of our U- S. and global business activities, the enactment of Pillar Two legislation could increase tax uncertainty and **could also** have a material effect on the Company’ s effective tax rate, financial position, results of operations, and cash flows. The Company will continue to monitor and reflect the impact of such legislative changes in future financial statements as appropriate. **We must obtain certain approvals and marketing clearances** **German tax authorities are currently performing a criminal investigation related to a series of intercompany loans** from 2016 and 2017 (the “ German Tax Investigation ”). **As of the date of this filing** , governmental authorities there have been no charges against the Company or current or former employees. **Potential outcomes of the German Tax Investigation involve a number of uncertainties** , including the FDA and similar health authorities in foreign countries to market and sell select products in those **relating to** countries. These agencies regulate the **application** marketing, manufacturing, labeling, packaging, advertising, sales and distribution of **tax law and** medical devices. The FDA enforces additional regulations regarding the safety of X- ray emitting devices. Various U- S. states also impose manufacturing , licensing, and distribution regulations. The FDA review process typically requires extended proceedings pertaining to the safety and efficacy of new products. A 510 (k) application is required to market certain classes of new or modified medical devices. If specifically required by the FDA, a pre- market approval, or PMA, may be necessary. Such proceedings, which must be completed prior to marketing a new medical device, are potentially expensive and time consuming. They may delay or hinder a product’ s timely entry into the marketplace. Moreover, there can be no assurance that the review **German Tax Investigation will be resolved favorably. Our management has devoted and may be required to further devote significant time and attention to the German Tax Investigation. If the German Tax Investigation is resolved against us, it could harm or our approval process reputation, business, ability to attract talent, particularly professionals with backgrounds in international tax and tax accounting, financial condition and results of operations. Additionally, while we cannot estimate our potential exposure at this time, we have already expended a significant amount of time and resources investigating and supporting requests for these products by the FDA or information from German tax authorities, and we expect to continue to do so. Accordingly, this investigation and any related litigation could distract management and entail risks and uncertainties, other -- the outcome of which could** applicable governmental authority will occur in a timely fashion, if at all, or that additional regulations will not be adopted or current regulations amended in such a manner as will adversely affect us **our results of operations and our reputation. For further information regarding the German Tax Investigation, see Note 21, Commitments and Contingencies, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10- K. On October 24, 2024, we announced the voluntary suspension of the sale and marketing of our direct- to- consumer Byte aligner systems and impression kits. In January 2025, we announced that Byte aligners would no longer be offered to new patients, and we now plan to utilize certain Byte resources elsewhere in the aligners portfolio to create orthodontic demand, support a digital clinical workflow, enhance the customer experience, and improve patient monitoring . The initial suspension** FDA also oversees the content of advertising and marketing **subsequent decisions regarding Byte products has had a materials- material impact on our results of operations** relating to medical devices which have received FDA clearance. Failure to comply with **The sales of Byte aligner systems and impression kits represented approximately 3 % of our annual revenue for the FDA year ended December 31, 2024, and the assets related to the Byte aligner business are approximately 1 % of the Company’ s assets** **advertising guidelines may result in the imposition..... fall into the category of Class I** as classified by the EU MDD were mandated to be certified under the new EU MDR. These regulations applied to all medical device manufacturers who market their medical devices in the EU and manufacturers were required to perform significant upgrades to quality systems and processes including technical documentation and obtain new certification under the EU MDR to continue to sell those products in the EU. Although all medical device manufacturers were required to certify their Class I products by May 2021, the EU MDR regulations for additional Classes of medical devices are mandated to be fully enforced by May 2024. This also includes completion of certified quality management systems to manufacturers quality management systems. On January 6, 2023, the EU Commission submitted a proposed amendment to extend the MDR transitional periods until December 31, 2027 **2024** for higher risk devices and December 31, 2028, for other medical devices to ensure continued access to medical devices for patients and to allow medical devices already placed on the market in accordance with the current legal framework to remain on the market. **We remain focused on ensuring also incurred charges relating to customer refunds and asset write- offs. For further information, see Note 18, Restructuring and Other Costs, in the Notes to Consolidated Financial Statements in Item 8 of this Form 10- K. There is no guarantee** that **we** all our products that are considered to be medical devices will be **successful** fully certified as

required by the EU MDR deadlines. Additionally, the UK has negotiated an exit from the EU, (commonly referred to as Brexit) and, as a result, the EU CE marking will be recognized in the UK through the earlier of the expiration of the product's CE certificate or **our endeavor** June 2028. After which, the UK may impose its own differing regulatory requirements for products being imported from the EU into the UK. Failure to **leverage Byte technologies** comply with these rules, regulations, self-regulatory codes, circulars and **capabilities** orders could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in federal and state health care programs, and could have a material adverse impact on our business. Also, these regulations may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could **is accretive to sales and profit. If we are unsuccessful in these efforts, we may be** require **required** us to make changes in operations or incur **additional significant impairment charges** substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private regulators could result in reputational harm and the incurring of substantial costs. In addition, **although we** many of these laws are vague or indefinite and have not been interpreted by the courts and have been subject **accepted any new patients since October 24, 2024, we will continue** to provide support frequent modification and varied interpretation by prosecutorial or **for non- contraindicated Byte aligner patients currently undergoing treatment. With respect to these patients, we continue to experience** regulatory **uncertainties** authorities, increasing compliance risks. **For example, Some some** state legislatures have passed legislation and other state legislatures have proposed legislation designed to preclude or significantly limit teledentistry, **and various state legislatures are continuing to consider such legislation**. Furthermore, our ability to conduct business in each state is dependent, in part, upon that particular state's treatment of remote healthcare and that state dental board's regulation of the practice of dentistry, each of which is subject to changing political, regulatory, and other influences. Some state dental boards established rules in a manner that purports to limit or restrict our **Byte ability to conduct our business as, which** currently **conducted focuses on the provision of Byte aligners to certain existing patients**. It is possible that the laws, rules and regulations governing the practice of dentistry and orthodontics in one or more states may change or be interpreted in a manner unfavorable to our business. If adverse laws or regulations are adopted or any such claims are successful, and we were unable to adapt our business model accordingly, our **current** operations in such states would be disrupted, which could have a material adverse effect on our business, financial condition, and results of operations. Third- party payors, including government health administration authorities, private health care insurers and other organizations, regulate the reimbursement of fees related to certain diagnostic procedures or medical treatments. Third- party payors are increasingly challenging the price and cost- effectiveness of medical products and services. While we cannot predict what effect the policies of government entities and other third- party payors will have on future sales of our products, there can be no assurance that such policies would not cause our revenue to decline. We manufacture and sell a wide portfolio of dental and medical device products. While we endeavor to ensure that our products are safe and effective, there **can be no assurance that there** may not be challenges from time to time regarding the **real or perceived** quality, health or environmental impact of our products or certain raw material components. **Adverse publicity about the quality or safety** of our products **may have an adverse effect on our brand, reputation and operating results. Legal and regulatory developments in this area may lead to litigation and / or product limitations or discontinuation**. We manufacture and sell dental filling materials that may contain bisphenol- A, commonly called BPA. BPA is found in many everyday items, such as plastic bottles, foods, detergents, and toys, and may be found in certain dental composite materials or sealants either as a by-product of other ingredients that have degraded, or as a trace material left over from the manufacture of other ingredients used in such composites or sealants. The FDA currently allows the use of BPA in dental materials, medical devices, and food packaging. Nevertheless, public reports and concerns regarding the potential hazards of BPA could contribute to a perceived safety risk for our products that contain **mercury or BPA**. **Adverse publicity about the quality or safety of our** **or other substances** products, whether or not ultimately based on fact, may have an adverse effect on our brand, reputation and operating results and legal and regulatory developments in this area may lead to litigation and / or product limitations or discontinuation. We are subject to federal, state, local and foreign laws, rules, regulations, self- regulatory codes, circulars, and orders relating to health care fraud, including, but not limited to, the U. S. Federal Anti- Kickback Statute, the UK Bribery Act 2010 (c. 23), Brazil's Clean Company Act 2014 (Law No. 12, 846) and China's National Health and Family Planning Commission ("NHFPCC **Healthcare Fraud Laws**") circulars No. 49 and No. 50. Some of these laws, referred to as "false claims laws," prohibit the submission, or causing the submission, of false or fraudulent claims for reimbursement to **federal, state and other** health care payors and programs. Other laws, referred to as "anti- kickback laws," prohibit soliciting, offering, receiving, or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for or recommending ordering, purchasing or leasing, of items or services that are paid for by **federal, state and other** health care payors and programs. The U. S. government has expressed concerns about financial relationships between suppliers and physicians and dentists. As a result, we regularly review and revise our marketing practices as necessary to facilitate compliance. In addition, under **Under** the reporting and disclosure obligations of the U. S. Physician Payment Sunshine Act and similar **foreign laws, rules, regulations, self- regulatory codes, circulars and orders, such as France's Loi Bertrand and rules issued by Denmark's Health Healthcare Fraud Laws and Medicines Authority**, the general public and government officials will be provided with access to detailed information with regard to payments or other transfers of value to certain practitioners (including physicians, dentists and teaching hospitals) by applicable drug and device manufacturers **subject to such reporting and disclosure obligations, including** which includes us. This information may lead to greater scrutiny, which may result in modifications to established practices and additional costs. Failure to comply with **Healthcare health care fraud Fraud laws Laws**, rules, regulations, self- regulatory codes, circulars and orders could result in significant civil and criminal penalties and costs, including the loss of licenses and the ability to participate in **governmental** federal and state health care programs, and could have a material adverse impact on our business. Also, these laws may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense

and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. In addition, many of these laws are vague or indefinite and have not been interpreted by the courts, and have been subject to frequent modification and varied interpretation by prosecutorial and regulatory authorities, increasing compliance risks. We cannot predict whether changes in applicable **Healthcare Fraud Laws, or the interpretation thereof, or changes in our services or practices in response, could adversely affect our business. Our business is subject to extensive, complex, and changing domestic and foreign laws, rules, regulations, self-regulatory codes, directives, circulars and orders which, or the interpretation thereof if not complied with, or changes in subject us to civil or or criminal penalties** services or marketing practices in response, could adversely affect our **or business other liabilities**.

We are subject to extensive domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders which are administered by various international, federal and state governmental authorities, including, among others, the FDA, the Office of Foreign Assets Control of the U. S. Department of the Treasury (“OFAC”), the Bureau of Industry and Security of the U. S. Department of Commerce (“BIS”), the U. S. Federal Trade Commission, the U. S. Department of Justice, the Environmental Protection Agency (“EPA”), and other similar domestic and foreign authorities. These laws, rules, regulations, self-regulatory codes, circulars and orders include, but are not limited to, the U. S. Food, Drug and Cosmetic Act, the EU MDD (and implementing and local measures adopted thereunder), the Federal Health Information Technology for Economic and Clinical Health Act (“HITECH Act”), the Federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), France’s Data Protection Act of 1978 (rev. 2004), the U. S. Foreign Corrupt Practices Act (the “FCPA”), the U. S. Federal Anti-Kickback Statute and similar international anti-bribery and anti-corruption laws, the Physician Payments Sunshine Act, regulations concerning the supply of conflict minerals, various **and increasingly fragmented** environmental regulations **such as the Federal Water Pollution Control Act (the “Clean Water Act”),** the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the “Health Care Reform Law”), **and regulations relating to trade, import and export controls and economic sanctions, and regulations relating to cybersecurity, including the EU’s Network and Information Security Directives, the EU’s Artificial Intelligence Act, and China’s Personal Information Protection Law.** Such laws, rules, regulations, self-regulatory codes, circulars and orders (“Applicable Laws”) are complex and are subject to change. The FCPA generally prohibits companies and their affiliates from making improper payment to non-U. S. officials for the purpose of obtaining or retaining business, and also includes ~~certain~~ books and records and internal accounting controls requirements. Our internal policies, procedures and Code of Ethics and Business Conduct mandate compliance with these anti-corruption laws. However, we operate in some countries known to experience corruption. Despite our training and compliance programs, we cannot provide assurance that our internal policies and procedures will always protect us from ~~violation~~ **violations** of such anti-corruption laws committed by our employees or affiliated entities or their respective officers, directors, employees and agents. Failure to comply with the FCPA and other laws governing the conduct of business with government entities **(including local laws), will may** subject us to criminal and civil penalties and other remedial measures, which could have a material adverse impact on our business, financial condition, results of operations and liquidity. Any ongoing investigation of ~~any~~ potential violations of the FCPA or other anti-corruption laws by the **United States** U. S. or foreign authorities could harm our reputation and have an adverse impact on our business, financial condition and results of operations. ~~On December 31, 2020, we acquired Byte, a leading provider in the direct-to-consumer, doctor-directed aligner market. Byte’s business in the United States is subject to various state laws, rules and policies which govern the practice of dentistry within such state. Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, which includes the oversight and control of each customer’s clinical treatment; however, there can be no assurance that such business model will not be challenged as the corporate practice of dentistry by state governmental authorities, trade associations, or others. Additionally, future legislative or regulatory changes within such states may have a negative impact on Byte’s business model. Compliance with the numerous applicable existing and new~~ **Applicable laws Laws**, rules, regulations, self-regulatory codes, circulars and orders could require us to incur substantial regulatory compliance costs. **For example, we are currently in the process of implementing enhancements to our post-market surveillance processes and reportability criteria, which has resulted in an increase in the number of regulatory reports that we have filed, including retrospective reports, for complaints regarding medical devices.** There can be no assurance that governmental authorities will not raise compliance concerns or perform audits to confirm compliance with such **Applicable laws Laws**, rules, regulations, self-regulatory codes, circulars and orders. For example, most of our products are classified as medical devices or pharmaceuticals, which are subject to extensive regulations **globally promulgated by the U. S. federal government, state governments and comparable regulatory agencies in other countries,** including the requirement to obtain licenses for the manufacture or distribution of such products. Failure to comply with **applicable Applicable laws Laws**, rules, regulations, self-regulatory codes, circulars or orders could result in a range of governmental enforcement actions, including fines or penalties, injunctions and / or criminal or other civil proceedings. Any such actions could result in higher than anticipated costs or lower than anticipated revenue and could have a material adverse effect on our reputation, business, financial condition and results of operations.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK We **may** experience significant fluctuations in quarterly sales and earnings due to several factors, some of which are substantially outside of our control, including but not limited to:

- general economic conditions, as well as those specific to the healthcare industry and related industries;
- changes in income tax laws and incentives that could create adverse tax consequences;
- the execution of restructuring plans;
- the complexity of our organization;
- our ability to supply products to meet customer demand;
- the timing of new product introductions by us and our competitors;
- the timing of industry trade shows;
- changes in customer inventory levels;
- developments in government or third-party payor reimbursement policies;
- changes in customer preferences and product mix;
- fluctuations in manufacturing costs;
- competitors’ sales promotions; and
- fluctuations in currency exchange rates.

As a result, we may fail to meet the expectations of investors and securities analysts,

which could cause our stock price to decline. Certain provisions of our Certificate of Incorporation and By-laws and of Delaware law could have the effect of making it difficult for a third party to acquire a controlling interest in us. Such provisions include, among others, a provision allowing the Board of Directors to issue preferred stock having rights senior to those of ~~the~~ **our** common stock and certain requirements which make it difficult for stockholders to amend our By-laws and prevent them from calling special meetings of stockholders. Delaware law imposes some restrictions on mergers and other business combinations between us and any “interested stockholder” with beneficial ownership of 15% or more of our outstanding common stock.

GENERAL RISKS Our business, operating results, financial condition and liquidity may be adversely affected by changes in global economic conditions, including inflation, supply chain disruptions, credit market conditions, levels of consumer and business confidence, and other factors that are generally beyond our control. ~~The~~ **We expect the** current global supply chain and labor market challenges and inflationary pressures ~~have negatively affected, and we expect~~ will continue to negatively affect our results of operations. Specifically, the Company continues to experience higher prices and supply chain disruptions for certain of our raw materials, particularly for electronic components, ~~and as well as wage inflation for direct labor~~. ~~As it pertains to demand for our products, certain~~ **Certain** dental specialty products and, dental equipment and related products that support discretionary dental procedures, especially elective procedures in implants and aligners, may also be **especially** susceptible to unfavorable changes in economic conditions. Decreases in consumer discretionary spending could negatively affect our business and ~~cause result in~~ a decline in sales and financial performance. Additionally, **high** interest rate ~~rates~~ **increases** have created financial market volatility, which could further negatively impact financial markets, ~~or~~ lead to an economic downturn or recession, and ~~tighten availability of, and increase the costs of capital for the Company~~. These and any other unfavorable economic conditions could increase our funding costs, limit our access to the capital markets or ~~cause result in a decision by~~ lenders not to extend credit to us. Tightening of credit in financial markets has ~~also~~ adversely impacted our customers’ and suppliers’ ability to obtain financing ~~for significant purchases and operations with acceptable terms~~ and could result in additional ~~or worsening~~ impacts in the future, including a decrease in or cancellation of orders for our products and services, inability of our customers to make payments, and increased risk of supplier financial distress. The Company has sought to offset the elevated costs resulting from raw material cost inflation with annual price increases but has been only partially successful. Should the higher inflationary environment continue, we may not be able to increase the prices of our offerings sufficiently to keep up with the rate of inflation. Any of the above factors could individually or in combination have a material adverse effect on our operating results, financial condition and liquidity. Our success is dependent on our ability to successfully manage our human capital through talent acquisition, engagement, development, and retention. To achieve our strategic initiatives, we need to attract, manage, and retain employees with the right skills, competencies, and experiences to execute our strategy and support the growth of the business. The failure to attract and retain such employees to fill key roles, ~~or to upskill employees to fill any potential skill gaps,~~ may adversely affect our business performance, competitive position, and future prospects. We also must retain a pipeline of team members to provide for continuity of succession for senior executive positions. To attract and retain qualified employees, we must offer competitive compensation and benefits and effectively manage employee performance and development. Leadership transitions or other senior management changes may adversely affect our ability to attract and retain talent. Our inability to attract and retain talent may negatively impact business continuity, new product launches, and innovation initiatives. Further, such organizational challenges may make it difficult to maintain our culture, resulting in employees not adhering to the desired values of the organization. We face the inherent risk of legal actions or claims, including purported securities class actions, investigations by governmental agencies, product liability claims, product recall actions, antitrust suits, customs proceedings, tax actions, commercial or contractual claims, employee benefit or discrimination lawsuits, actions based in environmental laws, and other matters. These actions or claims, regardless of their factual bases, might result in substantial costs, restrictions, or otherwise materially injure our business by harming our reputation or distracting our officers, management, and employees. The penalties imposed as a result of legal actions or claims might include fines, civil penalties, criminal penalties, injunctions, recalls, and other sanctions that may materially harm our business by reducing our ability to sell or promote our products or reducing our profits. We have insurance policies, including directors’ and officers’ insurance and product liability insurance, covering these risks in amounts that are considered adequate; however, we cannot provide assurance that the maintained coverage is sufficient to cover future claims or that the coverage will be available in adequate amounts or at a reasonable cost. Also, other types of claims asserted against us may not be covered by insurance. A successful claim brought against us in excess of available insurance, or another type of claim which is uninsured or that results in significant adverse publicity against us, could harm our business and our overall cash flows. Additionally, we include warranties on select products against defects in materials and workmanship, which are generally for a period of one year from the date of shipment or installation plus any extended warranty period purchased by the customer. The future costs associated with providing product warranties could be material. Successful product warranty claims brought against us could reduce our profits and / or impair our financial condition and damage our reputation. We have sales or operations in **approximately** more than 150 countries and our suppliers’ manufacturing facilities are in **multiple many** locations around the world. While we seek to mitigate our risks associated with climate events, we recognize that there are inherent climate-related risks regardless of where we conduct our businesses. Global climate change is expected to result in certain types of natural disasters occurring more frequently or with ~~more~~ **increased** intense **intensity and such** effects. ~~Any natural disaster, power outages or other~~ climate events ~~in such a location or the increased frequency of extreme weather~~ could disrupt the production and distribution of our products ~~in these locations~~. Current or future insurance arrangements may not provide protection for costs that may arise from such events, particularly if such events are catastrophic in nature or occur in combination. Accordingly, a natural disaster **impacting a significant manufacturing or distribution facility, besides potentially adversely impacting operations of key suppliers,** has the potential to disrupt our and our customers’ businesses and may cause us to experience work stoppages, project delays, financial losses and additional costs to resume operations, including increased

insurance costs or loss of **cover coverage**, legal liability and reputational losses. Increasing natural disasters in connection with climate change could also impact our third- party vendors, service providers or other stakeholders, including disruptions in supply chains, information technology or other necessary services for our Company. Many governments, regulators, investors, **employees, customers** and other stakeholders are increasingly focused on environmental, social and governance **considerations** (“ ESG ”) **considerations** relating to businesses, including climate change and, **pollution**, greenhouse gas emissions, human and civil rights, and diversity, equity and inclusion. The increased emphasis on ESG matters has resulted in, and may continue to result in, the adoption of laws and regulations, including additional reporting requirements, leading to increased compliance costs, as well as increased scrutiny regarding our ESG activities and disclosures, which may lead to increased litigation **risks**. We make statements about our ESG goals and initiatives through our Sustainability Report, our other non- financial reports, information provided on our website, press statements and other communications. Many of the statements in those voluntary disclosures are based on hypothetical expectations, assumptions, and predictions that may or may not be representative of current or actual risks or events or forecasts of expected risks or events, including the costs associated therewith. **Such expectations, assumptions, and predictions are uncertain and may be prone to error or subject to misinterpretation given the long timelines involved and the lack of an established single approach to identifying, measuring and reporting on many ESG matters.** Responding to these ESG considerations and **implementation**--- **implementing** of these goals and initiatives involves risks and uncertainties, may require investments, and depends in part on third- party performance or data that is outside our control which **may we have not independently verified or which cannot** be independently verified. Our **selected** disclosure framework may need to be changed from time to time due to evolving standards and practices, which may result in a lack of consistent or meaningful comparative data from period to period. In addition, our interpretation of reporting frameworks or standards may differ from those of others and such frameworks or standards may change over time, **any either** of which could **revise** result in **significant revisions** to our goals or reported progress in achieving such goals. Further, we cannot guarantee that we will achieve our ESG goals and initiatives. **Companies across all industries are facing increasing and evolving scrutiny relating to their ESG policies, initiatives and disclosures from governments, regulators, investors, consumers, employees and other stakeholders.** Increased and varied focus and activism related to ESG may hinder our **ability to attract or retain employees and** access to capital, as investors may reconsider their capital investment because of their assessment of our ESG practices. In addition, some stakeholders may disagree with our goals and initiatives. Any failure, or perceived failure, by us to achieve our goals, further our initiatives, adhere to our public statements, comply with **federal, state or international** ESG laws and regulations, or meet evolving and varied stakeholder expectations and standards could result in legal and regulatory proceedings against us and **could** materially adversely affect our business, reputation, results of operations, financial condition and stock price. **Federal** **Furthermore**, in recent years, “ anti- ESG ” sentiment has gained momentum across the United States, with several **state states** -, and **local the federal** governments- **government** are beginning to respond to climate change **having proposed or enacted anti- ESG policies, legislation or initiatives or** issues **issued related legal opinions** . This increased focus on sustainability **The Trump Administration also recently issued an executive order opposing diversity, equity and inclusion (“ DEI ”) initiatives in the private sector, which may draw additional attention to companies which provide products and services to the U. S. government. Such anti- ESG and anti- DEI policies, legislation, initiatives, litigation, legal opinions, and scrutiny could** result in new legislation or **our facing additional compliance obligations** regulations and customer requirements that could negatively affect us. Environmental laws -, for example, particularly with respect to climate change and the emission of greenhouse gases, are also becoming more stringent throughout the **subject of investigations, enforcement actions** world. We may incur additional costs or be required to make changes to our- **or litigation**, operations to comply with **any new regulations or customer requirements** **sustaining reputational harm** . Legislation or regulations that potentially impose restrictions, caps, taxes, or other controls on emissions of greenhouse gases such as carbon dioxide, could adversely affect our operations and financial results. **The** Recently, the **European Parliament Union** ’ s Corporate Sustainability Reporting Directive (“ CSRD ”) **came into effect, which** requires impacted companies, including multi- national companies with an EU presence, to make extensive sustainability and climate- related disclosure. The state of California has also enacted a series of **environmental** laws -, **related to climate disclosures with** which will **we are** require **required to comply** (i) disclosure of Scope 1, Scope 2 and Scope 3 GHG emissions by public and private companies with total annual revenues in excess of \$ 1 billion and that do business in California, (ii) disclosure of climate- related financial risks by public and private companies with total annual revenues in excess of \$ 500 million and that do business in California, and (iii) certain disclosures by businesses that market, sell and, in some cases, buy and use, voluntary carbon offsets, or that make certain environmental marketing claims in California. Additionally, **the SEC adopted** climate- related disclosure rules **have been proposed by the SEC, which** and, if adopted, would require the Company to make new climate- related disclosures . **Subsequently** , **including certain the SEC voluntarily stayed the implementation of such rules, pending the completion of judicial review by the Court of Appeals for the Eighth Circuit, and it is unclear whether and how the final rules will be implemented.** **climate- Climate** - related metrics and greenhouse gas emissions data, information about climate- related targets and goals, transition plans, if any, and comply with attestation requirements. The EU, California and (if adopted) SEC rules will impose increased- **increase** compliance costs and could lead to increased- **increase** litigation risks related to disclosures made pursuant to the rules, either of which could materially and adversely affect our financial performance. 35-34