

# Like all businesses, we face risks and uncertainties

## Our risk management process

Successful identification and management of existing and emerging risks is critical to the achievement of strategic objectives and to the long-term success of any business. Risk management is therefore an integral component of Smith+Nephew's Corporate Governance.

As in previous years our Enterprise Risk Management (ERM) process is based on a holistic approach to risk management. Our belief is that the strategic and operational benefits of proactively managing risk are achieved when ERM is aligned with the strategic and operational goals of the organisation. Our process and governance structure achieve this.

2021 has seen continuing improvement of risk management. We added dedicated Sustainability and Business Continuity risk champions and risk registers to the ERM scope. We increased collaboration between the Group Risk team and Business Area Risk Champions to discuss emerging risks more frequently. We improved reporting by adding quarterly qualitative updates on risk changes to the Audit Committee. A formal ERM survey was introduced in 2021 to identify improvement opportunities for 2022.

## Risk management life cycle

Annual improvement and refinement of our risk management ensures that it remains aligned with strategy and operations.

Our Risk Management Policy, sponsored by our Chief Executive Officer, is supported by an Enterprise Risk Management Manual and the Group Risk Team providing training to Business Area Risk Champions. As in prior years, risks continue to be managed through a 'top-down' and 'bottom-up' process, with regular oversight from the Executive Committee and quarterly reports to the Board Committees. An overview of our risk management life cycle is illustrated on this page.

## 2022 Risk Management Plan

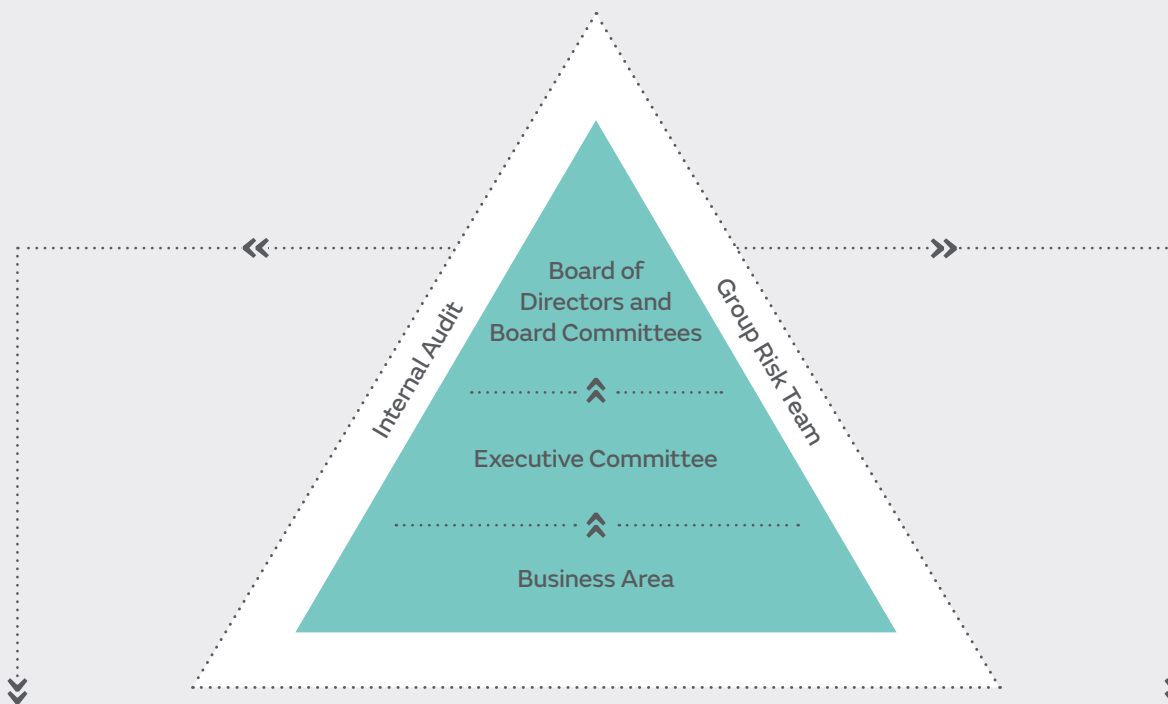
Our work will continue to evolve in 2022 with a particular focus on strengthening cross-functional risk management. This will include deep diving into specific risks with cross functional teams. We will work with the new sustainability risk champion to further develop the risk register in this area. The Group Risk team will also continue to influence decision making through effective challenge.



## Our risk governance framework

At the very top of our structure is our Board, setting our risk appetite and monitoring the application of our risk framework including strategy, execution, and outputs of risk reviews by the business and Group Risk Team. The Board cascades our risk appetite throughout our organisation through the Executive Committee, risk owner community and our management group. A formal 'bottom-up' exercise ensures that risks are escalated back through the process to our Board and are reflected in our Principal Risks as appropriate. Providing guidance and rigour across this process is our Executive Committee and the Group Risk Team.

At the third line of defence is our Internal Audit Function, providing an annual opinion on the effectiveness of our Risk Management process to the Executive Committee, chaired by the Chief Executive Officer, and then to the Board and its Committees.



### Board of Directors and Board Committees

- The Board is responsible for regular oversight of risk management, for our annual strategic risk review and for determining the risk appetite the organisation is willing to take in achieving its strategic objectives.
- The Board monitors risks through Board processes (Strategy Review, Disclosures, M&A, Investments, Disposals) and Committees (Audit and Compliance & Culture).
- The Audit Committee is responsible for ensuring oversight of the process by which risks relating to the Company and its operations are managed and for reviewing the operating effectiveness of the Group's Risk Management process.

### Executive Committee sitting as Group Risk Committee

- Identifies and ensures the management of risks that would prevent us from achieving our objectives.
- Appoints Business Area Risk Champions who are accountable for applying the Enterprise Risk Management Policy and Framework to produce the risk deliverables.
- Reviews external/internal environment for emerging risks.
- Reviews risk register updates from Business Area Risk Champions.
- Identifies significant risks and assesses effectiveness of mitigating actions.

### Group Risk Team

- Manages all aspects of the Group's approach to Enterprise Risk Management including design and implementation of processes, tools, and systems to identify, assess, measure, manage, monitor, and report risks.
- Facilitates implementation and co-ordination through Business Area Risk Champions.
- Provides resources and training to support process.
- Reports regularly on risk to the Executive Committee.
- Prepares Board and Group Risk Committee reports.

### Business Area Risk Champions

- Carry out day-to-day risk management activities.
- Identify and assess risk.
- Implement strategy and mitigating actions to treat risk within Business Area.
- Lead regular risk register updates.

### Internal Audit

- Provides independent assurance to the Board and Audit Committee on the effectiveness of the Group's Risk Management process.
- Provides annual assessment of effectiveness of Enterprise Risk Management.

# 2021 Principal Risks

We assess our Principal Risks in terms of their potential impact on our ability to deliver our business strategy. These links are highlighted across the following pages. The Principal Risks are presented in alphabetical order below. The COVID impact is included within the Principal Risks as appropriate rather than being separately identified.

## Business continuity and business change

Our business depends on our ability to plan for and be resilient in the face of events that threaten one or more of our key locations. Damage caused by natural disasters and severe weather can and do threaten our critical sites. Widespread outbreaks of infectious diseases, such as the COVID pandemic, create uncertainty and challenges for the Group and our customers.

Our business also requires continuous improvement and depends on our ability to execute business change programmes. The pace and scope of our business change initiatives may increase execution risk for the change programmes as well as for our business-as-usual activities.

### Examples of risks

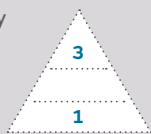
- Ongoing COVID disruption to manufacturing, distribution and support functions globally or regionally due to subsequent waves.
- Widespread outbreaks of infectious diseases (other than COVID).
- Natural disaster causes disruption to manufacturing at single or sole source facility (lack of manufacturing redundancy).
- Severe weather patterns, global temperature rise and sea-level rise caused by climate change or natural disaster causes damage to manufacturing or distribution facilities, impacting ability to meet customer demand.
- Disruption to the business due to critical system infrastructure and applications being unavailable.
- Significant change prevents our projects and programmes achieving the intended benefits and disrupts existing business activities.
- Failure to transform to achieve our sustainability targets.

### Actions taken by management

- Pandemic global, regional, and local crisis management governance in place.
- Processes and guidance on how to manage various scenarios associated with the ongoing COVID pandemic.
- Delivering Workplace Unlimited 'New Normal' programme.
- Controlled and phased return to office approach.
- Emergency and incident management and business recovery plans in place at major facilities and for key products and key suppliers.
- IT disaster recovery policy in place.
- Leadership taskforce established to resolve cumulative impact of global supply chain events.
- Project management governance and toolkits and project steering committee oversight to support successful execution of programme and projects.
- Executive level sustainability council oversees target setting and monitors progress.

Oversight  
Board

Link to Strategy  
1. Strengthen  
3. Transform



Change from 2020



### Risk change from 2020 key

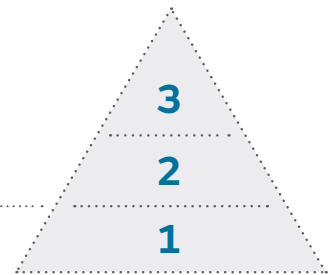
- Increased risk
 Reduced risk
 No change

## Our Strategy for Growth

**1** **Strengthen** the foundation to serve customers sustainably and simply

**2** **Accelerate** profitable growth through prioritisation and customer focus

**3** **Transform** our business through innovation and acquisition



» Further information on our Strategy for Growth can be found on page 7

## Commercial execution

The long-term success of our business depends on setting the right strategic priorities and executing on our plans to deliver those priorities in highly competitive markets. This requires effective communication and engagement with our customers, the right structures and capabilities across the Group and the ability to adjust and refine strategic priorities when necessary. Failure to set priorities and execute on those priorities will impact our ability to continue to grow our business and serve our customers.

### Examples of risks

- Failure to execute our strategy adequately from high-level ambition to specific actions to make the ambition a reality.
- Inability to keep pace with significant product innovation and technical advances to develop commercially viable products.
- Failure to engage effectively with our key stakeholders to meet their evolving needs leading to loss of customers.
- Failure to manage distributors effectively leading to stocking and compliance issues.
- Inability to satisfy customers' sustainability requirements and expectations.
- Limited healthcare professional access to medical education.
- Failure to achieve potential from acquisitions due to integration challenges.

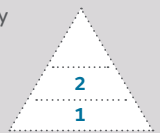
### Actions taken by management

- Strategic planning process clearly linked to business and Group risk.
- Continued new product launches and monitoring of innovation pipeline.
- Developed accessible sales information and training modules for sales staff.
- Improved healthcare professional engagement model.
- Policies and procedures to enhance channel management implemented.
- Virtual medical education processes put in place.
- Increased footprint of regional training centres.
- Deal-specific integration committee to review/approve integration plans and monitor ongoing processes.

Oversight Board

Link to Strategy  
 1. Strengthen  
 2. Accelerate

Change from 2020



## Cybersecurity

We depend on a wide variety of information systems, programs and technology to manage our business. We also develop and sell certain products that are or will be digitally enabled, including connection to networks and/or the internet.

Our systems and the systems of the entities we acquire may be vulnerable to a cyber attack, theft of intellectual property, malicious intrusion, data privacy breaches or other significant disruption. We have a layered security approach in place to prevent, detect and respond, to minimise the risk and disruption of any intrusions and to monitor our systems on an ongoing basis for current or potential threats.

### Examples of risks

- Loss of intellectual property/major data privacy breach or significant impact on business operations.
- Inadequate consideration of cybersecurity in the design of new products.
- Disruption to business operations due to a significant cybersecurity incident.
- Increased government focus on cybersecurity and changes in regulatory environment.

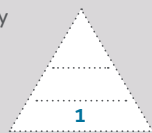
### Actions taken by management

- Ensured every user has access to and is using a secure Virtual Private Network (VPN) when connecting to Smith+Nephew networks to safeguard remote working.
- Continued security awareness activities including email communications, intranet posts, visuals, videos and more COVID-related email phishing training activities.
- Multi-factor authentication tools reduce the likelihood of remote attacks.
- Security information and event management (SIEM) in place to provide real-time analysis of security alerts generated by applications and network hardware.
- Regular penetration testing and frequent vulnerability scanning undertaken.
- Endpoint protection and intrusion detection/prevention implemented.
- Security governance structure in place including a Cybersecurity Steering Committee.
- Monitor developments from governments and raise changes and developments with Global IT Security.
- Cybersecurity Maturity Programme monitored by the Audit Committee.

Oversight  
Audit Committee

Link to Strategy  
1. Strengthen

Change from 2020



## Global supply chain

Our ability to make products available to customers in over 100 countries requires complex manufacturing and supply chain processes. Increased outsourcing, more sophisticated materials, and the speed of technological change in an already complex manufacturing process leads to greater potential for disruption in our supply chain. Supplier disruption, capacity constraints and the regulatory environment increase our exposure to supply chain disturbance.

Inflationary pressure on production and freight costs increases our risk of failing to achieve accelerated profitable growth.

### Examples of risks

- Disruption to manufacturing at a single source facility (lack of manufacturing redundancy).
- Manufacturing and supply chain capacity not adequate to support growth.
- Risks associated with the transition of warehouse and distribution activities to external supplier impacting inbound and outbound logistics.
- Supplier failure impacts ability to meet customer demand (single source supplier).
- Inadequate sales and operational planning impacts ability to meet customer demand for product.
- Excess inventory due to incorrect demand forecasts, inaccurate demand signals and unexpected changes in demand.
- Failure of suppliers and distribution partners to achieve and maintain regulatory compliance.
- Increasing costs of raw materials and freight.
- Increasing salary and wage costs for manufacturing and distribution employees and contractors.
- Severe weather patterns caused by climate change causes damage to manufacturing or distribution facilities, impacting ability to meet customer demand.
- Disruption to the business due to critical system infrastructure and applications being unavailable.
- Critical material shortages leading to supply challenges.
- Increased freight cycle times, increasing in-network inventory while disrupting customer supply.
- Labour attrition and delays in backfilling.

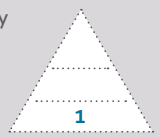
### Actions taken by management

- Delivering Global Operations transformation programme to optimise manufacturing and distribution centres and reduce single source limitations.
- Following Global Operations project management governance and toolkits to support successful execution of transformation programmes.
- Risk-based review programmes undertaken for critical suppliers.
- Business continuity plans developed and alternative source options identified for critical suppliers.
- Executive oversight of sales and operational planning.
- Increased coordination between commercial, supply chain and logistics to improve forecast accuracy.
- Comprehensive product quality processes in place from design to customer supply.
- Supplier contract agreements achieve and manage regulatory compliance.
- Initiatives to improve manufacturing efficiency and reduce overhead costs.
- IT disaster recovery policy in place.
- Leadership taskforce established to resolve cumulative impact of global supply chain events.

Oversight Board

Link to Strategy  
1. Strengthen

Change from 2020



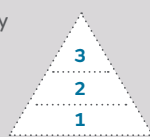
## Legal and compliance

We are committed to doing business with integrity and believe that ‘doing the right thing’ is part of our mandate to operate. We operate in multiple countries and regulatory authorities in each jurisdiction enforce an increasingly complex pattern of laws and regulations that govern the design, development, approval, manufacture, labelling, marketing, sale and operation of both traditional and digital healthcare products and services.

Operating across this complex and dynamic legal and compliance environment, which includes regulations on bribery, corruption, and privacy, increases the risk of fines, penalties, and reputational damage. We mitigate this through legal and compliance policies, procedures, training, and practices designed to prevent and detect violations of law, regulations, and industry codes.

**Oversight**  
Compliance & Culture Committee  
**Change from 2020**  
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**Link to Strategy**  
1. Strengthen  
2. Accelerate  
3. Transform



### Examples of risks

- Failure to act in an ethical manner consistent with our Code of Conduct and Business Principles.
- Violation of anti-corruption or healthcare laws, breach by employee or third-party representative.
- Misuse or loss of personal information of patients, employees, research subjects, consumers or customers results in violations of data privacy laws, including General Data Protection Regulations.
- The development, manufacture and sale of medical devices entail risk of product liability claims or recalls.

### Actions taken by management

- Group Compliance and Culture Committee oversees our ethical and compliance practices.
- Global compliance programme, policies and procedures.
- All employees required to undertake annual training, including privacy, and to certify compliance on an annual basis with our Code of Conduct and Business Principles.
- Issued an enhanced third-party guide to doing business with Smith+Nephew.
- Group monitoring and auditing programmes in place.
- Confidential independent reporting channels for employees and third parties to report concerns.
- Monitoring new regulatory and enforcement trends.

## Mergers and acquisitions

As the Group grows to meet the needs of our customers and patients, we recognise that we are not able to develop all the products and services required using internal resources and therefore need to undertake mergers and acquisitions in order to expand our offering and to complement our existing business. In other areas, we may divest businesses or products which are no longer core to our activities.

It is crucial for our long-term success that we make the right choices around acquisitions and divestments.

Failure to identify appropriate acquisition targets, to conduct adequate due diligence or to integrate them successfully or to deliver on the acquisition business case would have an adverse impact on our competitive position and profitability.

**Oversight**  
Board  
**Change from 2020**  
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**Link to Strategy**  
3. Transform



### Examples of risks

- Failure to identify appropriate acquisitions.
- Failure to conduct effective acquisition due diligence.
- Failure to integrate newly acquired businesses effectively, including integration with Group standards, policies and financial controls.
- Failure to deliver on plans to achieve the acquisition business case.

### Actions taken by management

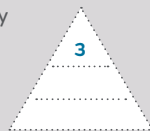
- Acquisition activity aligned with corporate strategy and prioritised towards products, franchises and markets identified to have the greatest long-term potential.
- Clearly defined investment appraisal process based on range of valuation metrics including return on invested capital, in accordance with Capital Allocation Framework and comprehensive post-acquisition review programme.
- Detailed and comprehensive cross-functional due diligence undertaken prior to acquisitions by experienced internal and external experts (including the integration team).
- Compliance risks included as part of due diligence reviews, integration plans and reporting for acquisitions.
- Deal-specific integration committee review, approval of integration plans and monitoring of ongoing process.
- Board reviews deals once a year.

## New product innovation, design & development including intellectual property

Our new product innovation pipeline is becoming larger and increasingly complex as we focus our efforts on high growth markets and procedure innovation using digital technologies such as connectivity, predictive data analytics and biologics. Consequently, we need to continue to better understand unmet customer needs, drivers of surgical efficiency and patient outcomes, and new country/regional regulations including requirements related to cybersecurity. If Smith+Nephew fails to protect and enforce its intellectual property rights successfully, its competitive position could suffer, which could harm its results of operations.

Oversight Board

Link to Strategy  
3. Transform



Change from 2020



### Examples of risks

- Failure to develop, partner or acquire a competitively differentiated innovation.
- Insufficient long-term planning to respond to competitor disruptive entries into marketplace.
- Inadequate innovation due to low Research & Development (R&D) investment, R&D skills gap or ineffective product development execution.
- Loss of market share due to critical gaps in product portfolio not filled.
- Loss of proprietary data due to natural disasters or failure of Product Lifecycle Management (PLM) systems.
- Competitors may assert patents or other intellectual property rights against the Group or fail to respect the Group's intellectual property rights.
- Failure to ensure sustainability in new products.

### Actions taken by management

- Continued product and technology acquisitions and product launches.
- Global R&D organisation and governance framework providing strategic direction for allocation of R&D investment across all businesses. Clear stage-gate process to continually evaluate R&D investment decisions and development of new products.
- Cross-functional New Product Design and R&D processes focused on identifying new products and potentially disruptive technologies and solutions.
- Replacing global PLM systems.
- Monitored external market trends and collated customer insights to develop product strategies.
- Careful attention to intellectual property considerations.
- Sustainability criteria built into New Product development processes.

## Political and economic

We operate a global business and are exposed to the effects of political and economic risks, changes in the regulatory and competitive landscape, trade policies, political upheaval, changes in government policy regarding healthcare priorities, increasing inflationary pressure and tax rates, preference for local suppliers, import quotas, war, economic sanctions and terrorist activities.

Oversight Board

Link to Strategy  
2. Accelerate



Change from 2020



### Examples of risks

- Global or regional recession and increasing macroeconomic controls due to COVID impact on customer financial strength.
- Global political and economic uncertainty and conflict.
- Failure to meet the sustainability targets and public policy changes.
- Implementation of healthcare reforms and/or protectionist measures, eg US/China trade, and regulations in local markets.
- Market access rights.
- Increases in import and labour costs.
- Increases in tariffs and restrictions on global trade.
- UK and EU disagree over implementation of Brexit.
- Inflationary pressures impacting raw materials, freight, salaries and wages.

### Actions taken by management

- Built sustainability strategy on our purpose, business strategy, and culture pillars, and tracked and benchmarked targets within the industry.
- Sustainability Council monitors public policy.
- Continued engagement with governments, administrations, and regulatory bodies to enhance education and advocacy efforts with policymakers.
- Actively participate in trade associations to enhance education and advocacy efforts with policymakers.
- Ongoing engagement and monitoring/lobbying on localisation initiatives.



## Pricing and reimbursement

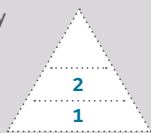
Our success depends on our ability to sell our products profitably, despite increasing pricing pressures from customers and the availability of adequate government funding to meet increasing demands for our products arising from patient demographic trends. The prices we charge are therefore impacted by budgetary constraints and our ability to persuade customers and governments of the economic value of our products, based on clinical data, cost, patient outcomes and comparative effectiveness.

We further face market changes, such as China volume-based procurement, consolidation of customers into buying groups, input cost inflation, increasing professionalisation of procurement departments and the commoditisation of entire product groups, which continue to challenge prices.

We mitigate this through portfolio mix and promotion of differentiated products, including a compelling clinical and economic value proposition.

Oversight  
Board

Link to Strategy  
1. Strengthen  
2. Accelerate



Change from 2020  
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### Examples of risks

- Reduced reimbursement levels and increasing pricing pressures.
- Systemic challenge on number of elective procedures.
- Lack of compelling health economics data to support reimbursement requests.
- Unilateral price controls/reductions imposed on medical devices.
- Price-driven tendering/ procurement processes.
- Volume-based procurement in China and other markets.
- Limited access to non-clinical decision makers.

### Actions taken by management

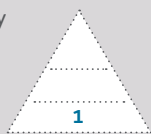
- Developed innovative economic product and service solutions for both established and emerging markets.
- Incorporated health economic components into the design and development of new products.
- Sales training to improve capability to communicate the clinical and economic value proposition to non-clinical decision makers.
- Implementing innovative contracting models designed to lessen the risk of adoption and coverage for healthcare providers and payers.
- Increased engagement with payer bodies to influence reimbursement mechanisms to reward innovation.
- Optimise portfolio mix and promote differentiated products.
- Consideration of price increases.

## Quality and regulatory

Global regulatory bodies continue to increase their expectations of manufacturers and distributors of medical devices. Our products are used in the human body and therefore patient safety is of paramount importance. The European Medical Device Regulation (EU MDR), the Medical Device Single Audit Programme and multiple other global regulations and standard changes have increased the focus on clinical and technical evidence, supplier controls and product performance transparency.

Oversight  
Compliance &  
Culture Committee

Link to Strategy  
1. Strengthen



Change from 2020  
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### Examples of risks

- Transition to EU MDR impacts ability to meet customer demand.
- Increase in time required by Notified Bodies to review product submissions and site quality systems' certification time for new products and EU MDR changes impacts ability to meet customer demand.
- Defects in design or manufacturing of products supplied to, and sold by, the Group could lead to product recalls or product removal or result in loss of life or major injury.
- Significant non-compliance with policy, regulations or standards governing products and operations regarding registration, design, manufacturing, distribution, sales or marketing.
- Failure to obtain proper approvals for products or processes.
- More stringent local requirements for clinical data across APAC markets.
- Changes to UK Medical Devices regulation following Brexit.

### Actions taken by management

- EU MDR Steering Group regularly monitors activities to comply with new requirements.
- Regular engagement with Notified Body, MHRA and regulatory representatives to monitor regulatory changes and understand interpretation of legislation.
- Comprehensive and documented product quality processes and controls from design to customer distribution in place, with the addition of cybersecurity to new product development projects for relevant products.
- Standardised monitoring and compliance with quality management practices through our Global Quality and Regulatory Affairs organisation.
- Incident management teams in place to provide a timely response in the event of an incident relating to patient safety.
- Governance framework in place for reporting, investigating and responding to instances of product safety and complaints.
- Local clinical evidence requirements are included in global new product development projects.

## Talent management

We recognise that people leadership, effective succession planning and the ability to engage, retain and attract talent is a key lever of success for our business. Recruitment and retention of top talent is a critical risk which requires a strong engagement process. Failure to do so places our ability to execute the Group strategy and to be effective in the chosen market/discipline at risk.

### Examples of risks

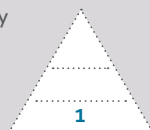
- Loss of key talent, high attrition and lack of appropriate succession planning in context of required skillsets for future business needs.
- Loss of competitive advantage due to an inability to attract and retain top talent.
- Loss of intellectual capital due to poor retention of talent.
- Failure to attract talented and capable candidates.
- Increased talent movement globally due to shifting personal work-life balance priorities.
- Increased salaries globally, particularly in the Research & Development, Quality and Regulatory Affairs, manufacturing and distribution functions.

### Actions taken by management

- Talent planning and people development processes well established across the Group.
- Talent and succession planning discussed annually by the Board and regularly by the Executive Committee and Nomination & Governance Committee.
- Identification of high value roles and ensuring that these roles are filled with our high-performance individuals with strong succession plans in place.
- Developed strategic skills resourcing plan by functional areas.
- Provided employees with access to tools and resources to manage their emotional, physical, and mental wellness.
- Ongoing segmentation of specific job roles and applying focused rewards to ensure we are competitive and attractive to candidates.

Oversight  
Board

Link to Strategy  
1. Strengthen



Change from 2020



## Taxation and foreign exchange

We operate a global business and are therefore required to comply with tax legislation in multiple jurisdictions and are also exposed to exchange rate volatility. Adverse changes to tax legislation, including those driven by international agreements such as the OECD proposed global minimum tax rate, and volatility in foreign currency exchange rates can impact our results and it may not be possible to fully mitigate against them.

### Examples of risks

- Potential for significant tax rate changes and/or base broadening measures in key jurisdictions where we operate including OECD proposals and US tax reform.
- Failure to comply with current tax laws.
- Transfer pricing policy not correctly implemented or monitored.
- Risk of adverse trading margins due to fluctuating foreign currency exchange rates between our main manufacturing operations (the US, UK, Costa Rica and China) and where our products are sold.
- Changing legislation in the US and other key markets may require changes to our operating model.

### Actions taken by management

- The Group Tax team continually monitor developments in tax legislation and obtain external advice where relevant.
- The Group Tax team, supported by external advisors, work closely with the business to implement agreed processes and procedures.
- A foreign exchange hedging programme is operated and is overseen centrally by the Group Treasury team.
- The Finance and Banking Committee monitors ongoing treasury and tax matters including foreign exchange exposure.
- Experienced Finance team.
- Internal Audit and Audit Committee oversight.
- Seeking appropriate independent third-party advice when required.

Oversight  
Audit Committee

Link to Strategy  
1. Strengthen



Change from 2020

Replaces Finance Risk

# Our Viability Statement

## How we assess our prospects

During the year, the Board has carried out a robust assessment of the principal risks affecting the Company, particularly those which could threaten the business model. These risks, and the actions being taken to manage or mitigate them, are explained in detail on pages 58–67 of this Annual Report.

In reaching our Viability Statement conclusion, we have undertaken the following process:

- The Audit Committee reviewed the Risk Management process at their meetings in February, April, July and December, receiving presentations from the Group Risk Team, explaining the processes followed by management in identifying and managing risk throughout the business.
- In May and October 2021, the Executive Committee (ExCo) met as a Risk Committee to review the 2021 Principal Risks (the top-down risk review process). The ExCo was asked to consider the significant risks which they believed could seriously impact the profitability and prospects of the Company and the principal risks that would threaten its business model, future performance, solvency or liquidity.
- All ExCo members nominated the Risk Champions and have worked with them to prepare risk registers. The Risk Champions nominated by the ExCo are senior, trained in risk management and most of the team have at least two years of experience in the Company.
- Using the outputs from the Business Area ‘bottom-up’ risk identification completed in September 2021 and following ‘top-down’ discussions with ExCo, the most significant risks affecting our organisation were presented to ExCo for approval in October as the draft 2021 Principal Risks facing the Company.
- ExCo agreed to retain 11 of the 12 Principal Risks from 2020. The Finance Risk is replaced by a Taxation and Foreign Exchange risk.
- ExCo considered the continuing impact of COVID, including within the viability scenario analysis.
- In assessing our TCFD risks we concluded that climate related risks are not significant in our viability horizon of three years. Nonetheless, we have included an extreme weather event in our Business Continuity and Business Change scenario.
- All relevant executives have attested alignment to the Group’s Enterprise Risk Management Process as part of the annual certification on governance, risk, and compliance.
- The Board debated and agreed the risk appetite for each of the Principal Risks in July 2021.
- Final Principal Risks were presented to the Audit Committee and the Board in February 2022 for their consideration and approval.
- Throughout the year, a number of reviews into different risks were conducted by the Board, the Audit Committee and the Compliance & Culture Committee looking into the nature of the risks and how they were mitigated.
- In carrying out scenario modelling of the Principal Risks on the following page we have also evaluated the impact of a severe but plausible combination of these risks occurring over the three-year period. We have considered and discussed a report setting out the terms of our current financing arrangements and potential capacity for additional financing should this be required in the event of one of the scenarios modelled occurring.
- We are satisfied that we have robust mitigating actions in place as detailed on pages 58–67 of this Annual Report. We recognise, however, that the long-term viability of the Company could also be impacted by other, as yet unforeseen, risks or that the mitigating actions we have put in place could turn out to be less effective than intended.

## Viability Statement

Having assessed the Principal Risks, the Board has determined that we have a reasonable expectation that the Company will be able to continue in operation and meet its liabilities as they fall due over a period of three years from 1 January 2022. In our long-term planning we consider horizons of between five and ten years. However, as most of our efforts are focused on the coming three years, we have chosen this period when considering our viability.

Our conclusion is based on the Strategic Plan reviewed by the Board in December 2021. We will continue to evaluate any additional risks which might impact the business model.

By order of the Board, on 22 February 2022.



**Susan Swabey**  
Company Secretary

## 2021 Scenarios modelled

### Scenario 1: Further COVID business disruption and pricing and reimbursement pressures

COVID disruption to elective surgery, manufacturing, distribution and support functions globally or regionally due to subsequent waves leading to a major loss of revenues and profits.

**Action taken:** We have modelled global volume reduction of 10% for the first six months of 2022, and a reduction of 5% for the last six months of 2022 with a similar assumption in 2023.

Reduced reimbursement levels and increasing pricing pressures.

**Action taken:** We have modelled price erosion of 1% for 2022 and 1% to 2023.

#### Link to strategy

- Accelerate profitable growth through prioritisation and customer focus.

#### Link to Principal Risks

- Business Continuity and Business Change.
- Global Supply Chain.
- Commercial Execution.
- Political and Economic.
- Pricing and Reimbursement.

### Scenario 2: Operational risk

Inability to keep pace with significant product, innovation, and technical advances to develop commercially viable products, losing significant market share to the competition.

**Action taken:** We have modelled 3% lower growth than planned for a key product range in the US in 2023 and 2024.

Disruption to manufacturing at a single source facility – resulting in our inability to manufacture several key products for one year.

**Action taken:** We have modelled the loss of strategic production machinery, resulting in the loss of production and sales for several key products for one year (2023).

Key Supplier Disruption – resulting in our inability to manufacture and supply a few key products for a full year.

**Action taken:** We have modelled an interruption to receiving goods from a key supplier for a period of one year in 2023.

Increases in raw materials, freight and labour costs.

**Action taken:** We have modelled an increase in our input costs by an additional 5% in 2022 and 2023, due to continued inflationary pressures.

Product Liability Claim.

**Action taken:** we have modelled a group of product liability claims resulting in a settlement agreement requiring cash payment in 2023 and 2024, without any insurance coverage.

#### Link to strategy

- Strengthen the foundation to serve customers sustainably and simply.
- Transform our business through innovation and acquisition.

#### Link to Principal Risks

- Commercial Execution.
- New Product Innovation, Design & Development including Intellectual Property.
- Global Supply Chain.
- Business Continuity and Business Change (weather related disruption).
- Political and Economic.
- Talent Management.

### Scenario 3: Tax, foreign exchange, legal, regulatory and compliance risks

Data privacy failure – giving rise to a significant fine or loss.

**Action taken:** We have modelled a one-off significant fine from regulator of 2% of revenue or loss resulting from a data privacy issue in 2023.

Failure to obtain proper regulatory approvals for products or processes impacting our ability to sell products.

**Action taken:** We have modelled the complete loss of revenue from a key product effective in mid-2022 for two years, and returning to lower volumes in mid-2024.

Risk of adverse trading margins due to fluctuating foreign currency exchange rates across our markets.

**Action taken:** We have modelled a reduction in profitability in 2023 and 2024 due to a weakening in other currencies relative to the US Dollar by 5%.

#### Link to strategy

- Strengthen the foundation to serve customers sustainably and simply.

#### Link to Principal Risks

- Legal and Compliance.
- Quality and Regulatory.
- Taxation and Foreign exchange.

### Scenario 4: Cybersecurity

Disruption to business operations due to a significant cybersecurity incident.

**Action taken:** We have modelled one of our key regions being unable to invoice also affecting shipping and tracking of deliveries for one month due to a disruption to our IT infrastructure in 2023.

#### Link to strategy

- Strengthen the foundation to serve customers sustainably and simply.

#### Link to Principal Risks

- Cybersecurity.

### Scenario 5: Mergers and acquisitions

Failure to integrate newly acquired business effectively to achieve expected growth.

**Action taken:** We have modelled a scenario of zero growth in a recently acquired business over the three-year period.

#### Link to strategy

- Transform our business through innovation and acquisition.

#### Link to Principal Risks

- Mergers and Acquisitions.