

Principal Risks and Uncertainties

Overview of our Principal Risks

The Group’s principal risks, our actions to mitigate those risks, a directional indication of whether the risks have increased, decreased or remained about the same, together with further commentary are set out in the table on the following pages. This list comprises the material risks post mitigating actions and is drawn from a more complete list of risks which are reviewed quarterly by the Board.

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Key Risk Trend

Increasing
 Stable
 Decreasing

“
 The experiences of Covid-19 and Brexit demonstrated the resilience of our business model and the agility and commitment of our employees”

Risk Appetite

Risk appetite can be defined as ‘the amount and type of risk’ that the Group is willing to take in order to meet their strategic objectives. The Board have applied a differentiated risk appetite to each major category of risk, i.e. Strategic, Operational, Financial & Compliance.

Levels of risk were considered against the following categories:

0. Avoid risk: Zero tolerance



1. Minimal risk: As little as reasonably possible



2. Cautious: Prepared to accept some limited loss



3. Open: Prepared to consider balance between risk and reward, invest for future return



4. Seek: Prepare to be innovative in pursuit of higher returns



5. Mature: Confident of setting high levels of risk appetite underpinned by rigorous processes and controls



Our Strategic risk appetite is assessed as level 4 (Seek) as we aim to be innovative in our specialist areas.

For Operational risks we adopt level 2 (Cautious) as our customer service is integral to our business model.

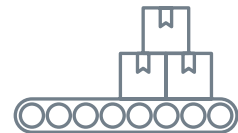
Our risk appetite for Financial & Compliance is level 1 (Minimal) as we work in a highly regulated industry and have valuable Intellectual Property to protect.

The acquisition of SLE Limited in the prior year transformed the scale of the Group and its risk profile. We are a medical technology business, supplying lifesaving and essential medical equipment for which there is ongoing strong demand and a high degree of regulation.

The experiences of Covid-19 and Brexit demonstrated the resilience of our business model and the agility and commitment of our employees. Our business operations continue in full, with the majority of our employees adopting our blended working policy.

Covid-19 still remains a risk to our business in the following areas:

► **Production:** We may find difficulties in the supply chain for materials and transport.



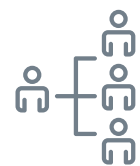
We have mitigated this by reviewing components and changing where necessary to components that are more readily available, placing forward orders, working with long standing suppliers and we have registered for Government backed schemes for essential suppliers for priority freight.

► **Employees:** Our employees may fall ill or have loved ones who need looking after.



Throughout the year we followed national guidance on home working where appropriate. This allowed us to keep our factories open and producing much needed medical technology and allowing to keep our teams safe. Since the start of the year, we have been encouraging our teams back to the offices and believe our compressed working week and hybrid working model will ensure that we remain efficient and productive as well as safe, giving our employees a better work/life balance.

► **Customers:** It is difficult to engage with customers as before as hospital staff concentrate on Covid-19 related activities. International travel is heavily affected and has limited face-to-face interaction with distributors.



We have implemented remote interaction through video conferencing platforms such as Teams and Zoom and have only visited for face-to-face meetings where appropriate.



Principal Risks and Uncertainties continued

Principal Risk

STRATEGIC



Loss of Key Distribution Principal agreements

The loss of any of the Group's largest distribution agreements to sell medical devices on behalf of third parties may have a material impact on the Group's business, prospects, financial condition or results of operations. Major account reviews take place regularly and plans are mutually agreed. Our strategy is based upon the added value of our supply chain and if necessary alternative product suppliers can be sourced.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Group is increasing the proportion of sales from products where we own the intellectual property to minimise this risk. The acquisition of SLE Limited has led to the termination of one of the largest distribution contracts (Vyaire) within the Group. Long-term contracts are typically signed but if a distributorship should be lost, all efforts will be made to replace the revenue with alternative products.</p>		<p>The proportion of Branded Product sales has increased from 31% to 55%.</p> <p>The Vyaire contract has been ended by mutual agreement.</p> <p>The distribution contract with Micrel has been signed for a further three years.</p>	

New Product Development

The Group invests in R&D projects in order to develop innovative new products. It works with an advisory panel in order to prioritise opportunity areas. Continued growth within existing customers depends upon the successful introduction of these new products. Concerns arise due to the late delivery of the projects, the changing regulatory landscape and competitive activity in the market-place which may make projects redundant.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>Projects are reviewed regularly by the Board and total R&D investment is increasing in the forthcoming year.</p> <p>The appointment of a Group Head of R&D and a Vice President - Clinical, Innovation and Compliance gives greater linkage between marketing plans and R&D priorities.</p> <p>The alignment of systems and processes across the Group has given greater visibility to tracking projects.</p>		<p>With the acquisition of SLE, the R&D team and its capability is greatly increased, but regulatory bottle necks are expected in the industry due to capacity within the regulators including those within clinical trials due to needing to catch up post Covid-19.</p>	

Principal Risk

STRATEGIC continued

Acquisitions

The strategy of the Group is to grow by a mixture of organic sales and acquisitions.

The Group may not be able to find acquisition targets at acceptable prices.

There is also a risk that management does not have adequate time and resources to identify, source, negotiate and integrate new acquisitions.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>Common business system and processes have been implemented across recently acquired sites and will comprise the basis for the integration of any future acquisitions.</p> <p>The Executive team have developed a robust model to evaluate acquisition prospects and identify synergies.</p>		<p>The SLE integration continues to proceed in line with best expectations and gives assurance in the quality of our business model, processes and team in relation to our evaluation of acquisitions</p>	

International Growth

The Group has a wide range of export markets which provide potential for growth.

Geopolitical conditions could have an impact on our markets.

Meaningful development of the US market, the largest medical device market in the world, may require significant investment in resources and may not generate the expected returns or take longer to crystallise those returns.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>It is impossible to plan for every eventuality however, early visibility, quick action and effective teamwork has been effective in minimising risks.</p> <p>A US market research project has commenced to determine the appetite for certain products within the Group.</p>		<p>The acquisition of SLE Limited has significantly expanded the Group's export markets. Export sales have increased from 34% to 57% of total.</p> <p>The Covid-19 pandemic was managed well within the Group but the full impact on the world economy remains unknown.</p> <p>It is too early to determine the impact of the conflict in Ukraine to the Group's business. The Group revenue in this region is less than 5% of total.</p>	

Principal Risks and Uncertainties continued

Principal Risk

STRATEGIC continued

Sustainability

The Group manufactures a range of disposable and capital equipment sourcing components from around the world and shipping finished goods globally.

Recently the NHS in England announced it intends to be Net Zero by 2045, with the NHS in Scotland wishing to be Net Zero by 2040. As other health systems around the world follow suit, the Group risks losing its ability to sell goods unless it embraces carbon reduction and adopts a sustainable approach to its operations

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Group has an Executive Director with responsibility for Sustainability (Brook Nolson). We are monitoring our Scope 1, 2, and 3 emissions and take action as appropriate to reduce them whilst growing our business.</p> <p>A new manufacturing and technology centre in Croydon is being developed with carbon reduction in mind, along with a policy for electric vehicles and other initiatives which are underway, including trialing a compressed working week and hybrid working.</p>	New	Our new manufacturing and technology centre in Croydon will be an example of best practice in low energy manufacturing. Other initiatives already undertaken would imply that the Group is ahead of where many SME Health Tech companies are in terms of their environmental impact.	

Principal Risk

OPERATIONAL

Dependence on third party suppliers and supply chain interruption

The operational capability of the Group depends critically on the efficiency and speed of its supply chain.



If there is any interruption to the supply of products or services by third parties, or those products or services are not as scalable as anticipated, or at all, or there are problems maintaining quality standards and delivering product to specification, or there are problems in upgrading such products or services, the Group’s business will be adversely affected.

Macro-economic factors like Brexit, Covid-19 and the conflict in Ukraine have provided challenges.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Group maintains appropriate stock levels of the most critical items to maintain customer service levels and mitigate this risk. These are constantly under review due to current issues in supply chain.</p> <p>Sourcing decision making is now embedded in operational planning processes. Supplier management is reviewed as part of Quality Management System.</p> <p>A disaster recovery plan exists and is reviewed regularly.</p> <p>The pandemic impact was beyond any scenarios envisaged. The Group demonstrated resilience due to systems, planning processes and quality of team.</p>		<p>Improved operational planning processes have reduced this risk during the year.</p> <p>The Group has implemented its ERP system into SLE Limited and Viomedex Limited to give greater visibility to planning, stock management and forecasting.</p> <p>Engineering work has reduced risk to certain components. It is expected that current supply chain issues of components widely reported will ease during 2022, although the recent conflict in Ukraine may make these issues last longer than thought at the beginning of the financial year.</p> <p>Supply chains are expected to be disrupted for longer due to the conflict in Ukraine.</p>	

Reliance on key individuals

The success of the Group depends crucially upon the expertise and relationships of the Directors and certain other senior employees. The loss of any of the key individuals could have an adverse effect on the Group.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Group has a strong, social purpose to save lives and improve outcomes which is motivating to employees. Rewards are competitive. A Long-Term Incentive Plan (“LTIP”) exists for all senior and key management roles.</p> <p>It is the Group’s policy to maintain a safe and pleasant work environment.</p> <p>The Group has an excellent benefits package and has recently introduced a compressed working week to add to flexible working to improve employee’s work/life balance.</p>		<p>The Remuneration Committee ensures remuneration packages retain and motivate the Executive Team and Senior Managers.</p> <p>Enlarged Group and strengthened management reduce potential impact of any loss.</p>	


Principal Risks and Uncertainties continued

Principal Risk

OPERATIONAL continued

Changes in legislation and regulation

The medical devices industry is highly regulated and each territory, in which the Group operates, is subject to its own stringent legal and regulatory regime to ensure the Group's products are safe and compliant. Regulatory approvals are required to market and sell medical devices into both the UK and export markets.



Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Group has stringent internal controls in order to comply with the relevant legal and regulatory conditions in the UK and in its export markets and a Quality Assurance and Regulatory Affairs department dedicated to liaising with the regulatory authorities to monitor any changes in conditions and ensure continuing compliance with the existing and new conditions. A Group Head of QARA oversees regulatory and compliance matters and investment in a new document management system will further reduce risks.</p>		<p>For the EU all products are certified to 2024 as part of the transition to MDR.</p> <p>The UKCA mark is required by June 2023. Preparation for key products to remain in the UK are underway and we are working with relevant Notified Bodies to ensure we will be able to meet this timetable.</p> <p>We are implementing a new document management system to improve traceability and compliance.</p>	

Health and Safety

The importance of Health and Safety is widely recognised across the Group.

Failure to adhere to health and safety regulations within the workplace not only puts our employees at risk but could carry serious financial, reputational, and legal risk.

We recognise that everyone has a right to work in a safe and pleasant environment free from adverse events.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>The Board requires Health and Safety to be discussed at the beginning of every Board meeting based on a report from the Executive Director responsible for Health and Safety (currently the Chief Operating Officer).</p> <p>The Group has a highly qualified Health and Safety Manager reporting directly to the Chief Operating Officer. The Group undertakes regular Health and Safety training for all employees using an on-line training portal that records training for audit purposes.</p> <p>Initiatives are run regularly to remind employees that Health and Safety is everyone's priority.</p>		<p>Improved procedures have been implemented and the Health and Safety capability significantly increased. Metrics are reviewed monthly by the Board and action taken should these start to show a negative trend.</p> <p>The business has a proactive approach to all aspects of Health and Safety and constantly reviews internal and external risks to enable training where appropriate.</p> <p>An employee Health and Safety focus group has been established and meets on a quarterly basis to ensure all areas of the business have a voice.</p>	

Principal Risk

OPERATIONAL continued

IT Systems and Cyber Security

The Group relies heavily on IT systems for its operational activities.

Two main areas of concern are:

- ▶ Human Error: People accidentally or deliberately manipulating data
- ▶ Third party hackers gain access to our systems or network.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
IT support is complemented by an external third party which allows a broader horizon scan of activity and access to best practices.		<p>The Audit Committee will carry out a “deep dive” review on cyber-security in 2022.</p> <p>By migrating all businesses onto a common IT system, we have harmonised controls and reporting.</p>	

Production moving to new facilities in 2022

The Group plans to move its main production facilities into a new, purpose-designed manufacturing and technology centre during Spring 2022 and there is a risk of short-term disruption to production and therefore sales during the Spring and Summer.

Mitigation	Movement in Year Risk Trend	Commentary	Potential Exposure
<p>We have a strategy that minimises any impact on manufacturing or despatch of our products.</p> <p>Our plan allows for a soft start allowing time to test and verify ever function and department prior to enacting a phased departmental move.</p> <p>With all the tooling and equipment being new we will not experience a delay due to transfer.</p> <p>We have increased production to hold slightly higher levels of finished goods in stock.</p> <p>Final transfer of the manufacturing environment will not complete until all the new systems are fully operational.</p> <p>Due to the introduction of our ERP and new automated warehousing systems, we are able to commence stocking in the new facilities at the same time as continuing warehousing from the current locations.</p>	New	<p>Led by the Chief Operating Officer, the H&S, Production Engineering, Facilities, IT, QA/RA and Manufacturing Teams, are represented at the construction planning and programming fortnightly meetings to ensure that integration is as seamless as possible.</p> <p>Representation and management of the contracts is done with a professional design team, Chief Operating Officer, and the Project Managers.</p>	