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# Principal Risks and Uncertainties

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.

## 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 risks 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 IP to protect.

The acquisition of SLE Ltd in the year has transformed the Group and its risk profile but we remain a medical technology business, supplying lifesaving and essential medical equipment for which there is ongoing strong demand and a high degree of regulation.

The experience of Covid-19 and Brexit demonstrated the resilience of our business model and the agility and commitment of our staff. Our business operations continue in full, albeit via significant remote working.

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 placing forward orders, working with long standing suppliers and have registered for Government backed schemes for essential suppliers for priority freight.

- **Staff:** Our staff may fall ill or have loved ones who need looking after.

We have a flexible approach to home working in line with UK Government advice. We have provided all staff with PPE (Personal Protective Equipment) and in-house test kits. We have shift work in the factories and social distancing in offices.

- **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 Risk	Mitigation	Movement in Year	Commentary
<b>STRATEGIC</b>			
<p><b>Loss of Key Distribution Principal agreements</b></p> <p>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.</p>	<p>It is the Group's intention to increase the proportion of sales from products where we own the intellectual property to minimise this risk. The acquisition of SLE Ltd has led to the planned termination of one of the largest distribution contracts (Vyaire) within the Group which will allow the Group to sell competing products into the UK and Ireland as well as expand sales internationally under its own brand. Long-term contracts are typically signed but if a distributorship be lost, all efforts will be made to replace the revenue with alternative products.</p>		<p>The acquisition of SLE Ltd has led to a significant increase in the proportion of sales manufactured in-house.</p> <p>The Vyaire contract has been ended by mutual agreement (post year-end).</p> <p>The distribution contract with Micrel has been signed for a further three years (post year-end).</p>
<p><b>New Product Development</b></p> <p>The Group invests in R&amp;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.</p>	<p>Projects are reviewed regularly by the Board and total R&amp;D investment is increasing in the forthcoming year.</p> <p>The appointment of a Group Head of R&amp;D and a Vice President - Clinical, Innovation and Compliance will give greater visibility on project delivery.</p>		<p>With the acquisition of SLE, the R&amp;D team and its capability is greatly increased, but regulatory changes still represent significant challenges.</p>
<p><b>Acquisitions</b></p> <p>The strategy of the Group is to grow by a mixture of organic sales and acquisitions.</p> <p>The Group may not be able to find acquisition targets at acceptable prices. Capital market appetite for micro-cap businesses to raise funds may change or macro-economic or political issues may impact on stock markets and there is a risk that the Group may not be able to fund some of the acquisitions it wishes to target.</p> <p>There is also a risk that management does not have adequate time and resources to identify, source, negotiate and integrate new acquisitions.</p>	<p>A new common business system and processes are being implemented across recently acquired sites and will comprise the basis for the integration of future acquisitions.</p> <p>The Executive team have developed a robust model to evaluate acquisition prospects and identify synergies.</p> <p>With the appointment of a COO to the Board, greater resources across a broader skill set have been secured.</p>		<p>The SLE integration is proceeding in line with best expectations and gives assurance in the quality of our business model, processes and team.</p>

## Principal Risks and Uncertainties continued

Principal Risk	Mitigation	Movement in Year	Commentary
<b>STRATEGIC</b> continued			
<p><b>International Growth</b></p> <p>The Group has a wide range of export markets which provide potential for growth.</p> <p>Geopolitical conditions could have an impact on our markets.</p> <p>Meaningful development of the USA 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.</p>	<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 been commenced to determine the appetite for certain products within the Group.</p>		<p>The acquisition of SLE Ltd has significantly expanded the Group's export markets and sales, providing both risk and opportunity.</p> <p>Brexit has been managed well using cross-company skills.</p> <p>The Covid-19 pandemic was managed well within the Group but the full impact on the world economy remains unknown.</p>
<b>OPERATIONAL</b>			
<p><b>Dependence on 3rd Party suppliers</b></p> <p>The Group's business depends on products and services provided by third parties. 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.</p>	<p>The Group maintains appropriate stock levels of the most critical items to maintain customer service levels and mitigate this risk.</p> <p>A COO has been appointed to ensure high quality operational management and planning.</p> <p>Quality Management Systems and processes are embedded in the Group's working practices.</p>		<p>Combined with the improved operational planning processes this risk has reduced during the year.</p> <p>The Group plan to implement its ERP system (Priority) into SLE Ltd to give greater visibility to planning, stock management and forecasting.</p>
<p><b>Reliance on key individuals</b></p> <p>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.</p>	<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>Executive salaries have been enhanced following acquisition of SLE Ltd.</p>		<p>A culture of engagement and recognition exists, and it is the Group's policy to maintain a safe and pleasant work environment.</p> <p>With a strengthened second tier management this risk has reduced.</p>
<p><b>Changes in legislation &amp; regulation</b></p> <p>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. Regulatory approvals are required to market and sell medical devices into both the UK and export markets. The risk is that new, stricter regulations prevent product introductions or delay them due to delays in approval. In the EU the Medical Device Regulation ("MDR"), which all new medical devices must comply to, has been delayed until May 2021.</p>	<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. The Group has 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. The Group has developed a detailed product-by-product plan for adoption of the MDR.</p>		<p>The Group has strong processes and resources but there is a level of reliance on adequate resources being available within regulatory authorities which is beyond our control.</p>

Principal Risk	Mitigation	Movement in Year	Commentary
<b>OPERATIONAL</b> continued			
<p><b>Competition</b></p> <p>The Group operates in a highly competitive market and may face competition from products designed, marketed and supplied by companies with significantly greater resources.</p>	<p>Exceptional customer service and short lead times provide barriers to competition. We have innovative products, that are niche in our field, helping to add value to our sales call and improve engagement with key decision makers. We work closely with key opinion leaders in neonatology. Our 24/7 customer service is a differentiator which is actively promoted.</p>		<p>No competitor provides products across our entire range. There have been no notable new entrants into the neonatal intensive care market during the year.</p>
<p><b>IP, data integrity and security</b></p> <p>The Group has intellectual property that it needs to protect. This can be in the form of innovative ideas, marketing specifications, and customer requirements. Our patents and controls may not prevent competitors from independently developing or selling products and services similar to ours, and there can be no assurance that the resources invested by us to protect our Intellectual Property will be effective, particularly in new markets. All companies are increasingly exposed to threats to access and steal data.</p>	<p>The Group maintains a register of Intellectual Property and reviews its patents and controls on a regular basis. Key strategic markets are prioritised for protection. The Group has deployed a number of measures to strengthen its protection against cyber security. These include systems access controls, staff training, passwords, updating policies and procedures.</p>		<p>The Group obtained Cyber Essentials accreditation during April 2021. The continuing development of IT threats against businesses in general leads us to view this risk as having increased for all companies.</p>
<p><b>Health and Safety</b></p> <p>The importance of Health &amp; Safety is widely recognised across the Group.</p> <p>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.</p> <p>We recognise that everyone has a right to work in a safe and pleasant environment free from adverse events.</p>	<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 COO).</p> <p>Additionally, and subsequent to the acquisition of SLE Ltd, the Group has appointed a highly qualified Health and Safety Manager reporting directly to the COO. The Group undertakes regular Health and Safety training for all staff.</p>		<p>The acquisition of SLE Ltd's manufacturing facilities have significantly increased this risk.</p> <p>The appointment of a senior Health, Safety and Sustainability Manager has led to improved procedures have been implemented and the capability significantly increased.</p> <p>The Board will monitor the situation closely during the year.</p>