Signature of the Group QA, RA & Technical Manager:	**Signature of the Managing Director:**
	

Supermax Healthcare Limited (the 'Organisation') aims to provide defect free products and services to its customers on time and within budget. Supermax Healthcare (Supermax Healthcare Ltd and Supermax Healthcare (Europe) Ltd) is an Importer and Legal Manufacturer of some products, and is in control of storage and distribution of medical examination gloves and Personal Protective Gloves.

The Organisation is committed to and operates a Quality Management System in compliance with the requirements of ISO 9001:2015 and ISO 13485: 2016. The business is further committed to reviewing and maintaining the effectiveness of the QMS, and undertakes to review resource requirements accordingly.

Supermax Healthcare undertakes to supply only safety equipment and/or related services that fully comply with the standards and regulations and claims made relating to those products and/or related services. Where appropriate, Supermax Healthcare will maintain up to date technical files and associated documentation to ensure that regulatory compliance information can be supplied upon request. The business will maintain a policy of full compliance with regulations all of the time, knowing that the safety of Public (including users, professionals and patients) is the key driver behind the regulations.

Where products are sourced from external organisations which hold technical files relating to the products being offered, Supermax Healthcare will request confirmation that these files are current, complete, contain appropriate conformity assessment information and, where relevant, regulatory compliance certificates and will take all necessary steps to confirm the validity of the compliance documentation held by that external supplier in respect of the products being sourced.

Where services are provided related to safety equipment sourced from external organisations, Supermax Healthcare will maintain approval from the manufacturer that the services provided are assessed and approved by the external organisation.

The business operates in a highly regulated marketplace, with on-going compliance with EU2016/425 PPE regulation, as amended, and the UK equivalent of the same name; and with the Medical Device Regulations EU2017/745, and the Medical Device Regulations 2002 as amended in the UK. As such the business is committed to the continued compliance of all business regulatory requirements.

The management is committed to:

1. Develop and improve the Quality Management System.
2. Continually improve the effectiveness of the Quality Management System.
3. The enhancement of customer satisfaction.
4. Full compliance with applicable legislation and Regulatory best practice and the spirit of the law.
5. Ensure that customer needs and expectations are determined and fulfilled with the aim of achieving customer satisfaction.
6. Communicate throughout the Organisation the importance of meeting customer needs and all relevant statutory and regulatory requirements.

7. Establish the Quality Policy and to set Quality Objectives at relevant functions, levels and processes.
8. Ensure that the Management Reviews set and review the Quality Objectives, and report on the internal audit results as a means of monitoring and measuring the processes and the effectiveness of the Quality Management System.
9. Ensure the availability of resources.

The structure of the Quality Management System is defined in the Quality Manual.

All personnel understand the requirements of this Quality Policy and abide with the contents of the Quality Manual. The Organisation complies with all relevant statutory and regulatory requirements. The Organisation constantly monitors its quality performance and implements improvements when appropriate.

This Quality Policy is regularly reviewed in order to ensure its continuing suitability.

Copies of the Quality Policy are made available to all members of staff and to relevant interested parties. Copies of the minutes of Management Reviews, or extracts thereof, are provided to individual members of staff in accordance with their role and responsibilities as a means of communicating the effectiveness of the Quality Management System.

1.1 Achieve "Buy in"

Supermax Healthcare Ltd has ISO 9001 and is ISO 13485 certified. ISO 9001 is the Business Management system implemented by many companies globally. ISO 13485 is the Business Management System standard for medical devices (such as Examination Gloves).

ISO 13485 certification supports medical device manufacturers, importers and Authorised Representatives in implementing a QMS that creates and maintains the efficacy of their processes, ensuring the safety of users of the products. It ensures the consistent design, development, storage and distribution, and investigation of Non-Compliance through to the disposal of medical devices that are safe for their intended purpose. The ISO 13485 standard also provides a planned structure and realistic foundation to stick to UK, EU or global medical device directives, regulations, protocols, and responsibilities. The standard is effectively legally required in full, to be implemented for sale of our products into our markets, as it demonstrates compliance with EU 2017/745 Medical Device Regulation, Article 10(9) and Article 16).

1.2 Managing Director

The Group Managing Director has set the tone for the business to follow ISO 9001 and ISO 13485 as well as all applicable legislation and policies and procedures to ensure that the risks of business operations are Eliminated, Substituted or Reduced or effectively managed. It is responsibility of the Managing Director to ensure business compliance and business governance is adhered to at all times.

1.3 Climate Change Consideration

The International Organization for Standardization (ISO) introduced a groundbreaking amendment to integrate climate change considerations into various Management System Standards.

1.3.1 Clause 4.1 Relevance of climate change: Organisations must assess if climate change is a relevant issue for their operations and context.

- This assessment should involve a thorough analysis of how climate change impacts various aspects of their business environment, including supply chain dynamics, regulatory compliance, and consumer behaviour. By understanding these effects, organisations can develop more resilient processes and adapt their strategies to

mitigate risks associated with climate change, ultimately ensuring long-term sustainability and competitiveness in their respective markets.

1.3.2 Clause 4.2 Stakeholder expectations: Relevant interested parties can have requirements related to climate change.

- Various stakeholders, including businesses, government agencies, and non-profit organizations, may have distinct requirements and considerations related to climate change. These requirements can encompass regulatory compliance, sustainability initiatives, and adaptation strategies aimed at mitigating the impacts of climate change on their operations and communities.

Supermax Healthcare is deeply committed to addressing the challenges posed by climate change and recognises its significant impact on public health and the environment. The organisation actively implements sustainable practices and eco-friendly initiatives to minimise its carbon footprint.

1.4 Senior Management Team

The Senior Management Team are responsible for ensuring that the activities under their control, and their teams follow the principles of this policy and ISO 9001 and ISO 13485 set by the business. Any KPI or projects that are required by the business to achieve this should be maintained and reported back to the business.

All defined quality objectives, targets and improvement actions related to departmental activities must be regularly reviewed, and reviews and progress recorded based on SMART Objectives and Plan Do Check Act (PDCA) principles.

Decision making by Managers and Leaders should include Quality considerations as a priority in addition to Cost, Environmental, Ethical and Safety considerations.

Any Non-Conformities, CAPA, audit results, records, or other routine systems required should be attended to, rectified and responded to in good time by the appropriate Manager.

1.5 Senior Manager Responsible

The Group QA, RA & Technical Manager, supported by the Group QA, RA & Compliance Executive and team, is responsible for the implementation, maintenance and monitoring of Quality Policies and business Management Systems (QMS), and Regulatory systems to effectively roll out to the business, and for reporting results to the business.

In addition to the Quality assurance function the Group QA, RA & Technical Manager, supported by the team is responsible for Environmental and Ethical sustainability practices, Health and Safety and regulatory compliance, as specified below.

The Group QA, RA & Technical Manager requires support from other Senior Leaders and staff within the business and has been empowered to request this as appropriate. The Group QA, RA & Technical Manager sits on the Senior Leadership Team, and directly feeds back Quality issues and improvements on a routine basis.

The business strategy for Regulatory Compliance, business Management systems and ISO 13485 and ISO 9001 will be communicated to the Senior Leadership team, to staff, and through the supply chain and on our internet site as applicable.

Under the UK and EU regulations, the duties of the person responsible for regulatory compliance include, but are not limited to:

- *The conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released.*
- *The technical documentation and the EU declaration of conformity are drawn up and kept up-to-date.*
- *The post-market surveillance obligations are complied with in accordance with Article 10(10) of the EU 2017/745 on Medical Devices and the UK Medical Device Regulations UK Statutory Instruments 2024 No. 1368.*
- *The reporting obligations referred to in Article 87 to 91 of the EU 2017/745 and equivalent UK legislation are fulfilled.*

The person responsible for regulatory compliance shall suffer no disadvantage within the organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organisation.

1.6 Empowerment of High Performing & Trained staff

The business will look to ensure that staff have access to the relevant level of information and awareness. The business looks to do this by:

- Training and encouraging internal business team to follow business practices and routines.
- Communicate the Quality policy to all staff, suppliers and stakeholders.
- Retain qualified and competent staff engaged with Quality standards.

2.0 REVISION HISTORY

Revision No.	Summary of change	Change Control No:	Date:	By:
11	Update to include BSIF requirements	135	31/03/2023	LK
12	Update to the Policy in line with current Policy requirements for the business.	174	30/08/2023	DT
13	Update to Policy to further explain legal responsibility.	247	30/08/2024	DT
14	Climate change consideration has been added to the policy	284	07/07/2025	EM
15	Correction of Importer / Legal Manufacturer Scope	290	08/08/2025	DT