Quality Manual

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John Weiss & Son Limited

Edinburgh Way,
Harlow, Essex,
CM20 2TT, UK
Tel: +44 (0) 1279 414 969
Fax: +44 (0)1279 635232

Approved by:

Gino Ostacchini
Managing Director
Clement Clarke Holdings Ltd

Dean Johnson
Managing Director
John Weiss & Son Ltd
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## Section 1 - Scope

John Weiss and Son Ltd (JW) maintains compliance with the applicable Regulations and Standards for the design, manufacture, distribution of sterile and non-sterile instruments for use in Ophthalmic and ENT procedures and for the repair of Ophthalmic and ENT instruments to BS EN ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory purposes for countries in which devices are distributed. This includes but is not limited to:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Country</th>
<th>Competent Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARE</td>
<td>UNITED ARAB EMIRATES</td>
<td>Ministry of Health &amp; Prevention</td>
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<tr>
<td>AUS</td>
<td>AUSTRALIA</td>
<td>Australian Therapeutic Goods (ATG)</td>
</tr>
<tr>
<td>AUT</td>
<td>AUSTRIA</td>
<td>Federal Ministry of Health Department III/3 Pharmaceuticals and Medical Devices (BMG)</td>
</tr>
<tr>
<td>BEL</td>
<td>BELGIUM</td>
<td>Federal Agency for Medicines and Health Products (FAMHP)</td>
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<td>BHR</td>
<td>BAHRAIN</td>
<td>National Health Regulation Authority (NHRA)</td>
</tr>
<tr>
<td>CAN</td>
<td>CANADA</td>
<td>Health Canada, Health Products and Food Branch, Therapeutic Products Directorate, Medical Devices Bureau</td>
</tr>
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<td>CHE</td>
<td>SWITZERLAND</td>
<td>Swissmedic, Swiss Agency for Therapeutic Products</td>
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<td>CYP</td>
<td>CYPRUS</td>
<td>Cyprus Medical Devices Competent Authority</td>
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<tr>
<td>CZE</td>
<td>CZECH REPUBLIC</td>
<td>Ministry of Health Department of Pharmacy, Medical Devices Unit</td>
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<tr>
<td>DEU</td>
<td>GERMANY</td>
<td>Federal Institute for Drugs and Medical Devices (BFARM)</td>
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<td>DNK</td>
<td>DENMARK</td>
<td>Danish Medicines Agency Pharmacovigilance and Medical Devices</td>
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<td>ESP</td>
<td>SPAIN</td>
<td>Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</td>
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<tr>
<td>FIN</td>
<td>FINLAND</td>
<td>Valvira – National Supervisory Authority for Welfare and Health</td>
</tr>
<tr>
<td>FRA</td>
<td>FRANCE</td>
<td>Agence nationale de sécurité du médicament et des produits de santé (ANSM)</td>
</tr>
<tr>
<td>GBR</td>
<td>UNITED KINGDOM</td>
<td>Medicines &amp; Healthcare Products Regulatory Agency (MHRA)</td>
</tr>
<tr>
<td>GRC</td>
<td>GREECE</td>
<td>National Organization for Medicines (EOF)</td>
</tr>
<tr>
<td>HKG</td>
<td>HONG KONG</td>
<td>Department of Health (DOH), Medical Device Control Office (MDCO)</td>
</tr>
<tr>
<td>HUN</td>
<td>HUNGARY</td>
<td>Health Registration and Training Centre, Department of Medical Devices</td>
</tr>
<tr>
<td>IDN</td>
<td>INDONESIA</td>
<td>Ministry Of Health Republic Of Indonesia (KEMKES)</td>
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<tr>
<td>IRL</td>
<td>IRELAND</td>
<td>Health Products Regulatory Authority (HPRA)</td>
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<td>IRQ</td>
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<td>Ministry of Health - KIMADIA</td>
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<tr>
<td>ISL</td>
<td>ICELAND</td>
<td>Icelandic Medicines Agency</td>
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</table>
### Standard Operating Procedures

Standard Operating Procedures are written to comply with applicable regulations, standards and guidance documents, this includes processes which are not performed by JW e.g. manufacture through Virtual Manufacturing Agreements (VMA) to which JW are legally responsible for the products.

Compliance to Standard Operating Procedures ensures that products conform to the requirements of these applicable regulations and current legislation.
Directive 93/42/EEC Annex II

Excluding Section 4

Single Use Sterile Corneal Trephines

Single Use Sterile Cauteries for cauterising small blood vessels in the eye

Single Use Sterile Orbital Implants

Single Use Non Sterile Tear Duct Tubes

Directive 93/42/EEC Annex V

Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions for the following products:

Sterile ophthalmic drapes

Sterile Eye shields

Sterile Ophthalmic & ENT sponges

Exclusions

No exclusions are taken to the requirements listed in the BS EN ISO 13485:2016 standard at this time.

Non-applicability

The following sections of the BS EN ISO 13485:2016 standard are non-applicable for John Weiss & Son Ltd:

Section 2 - Reference

Introduction & Company Profile

John Weiss & Son Ltd is world renowned for the manufacture and distribution of high quality microsurgical instruments. John Weiss & Son Ltd focuses on the individual requirements of both the professional and the patient.

Product Listing

- Forceps
- Needle Holders
- Scissors
• Choppers Hooks and Probes
• Specula
• Lid Instruments
• Oculoplastic and Lacrimal
• Vitreoretinal
• Specialist Instruments
• Trays
• Cannulae
• Disposables
• ENT Instruments
• Distributor Lines

In addition John Weiss & Son Ltd carry a number of virtual manufactured products. These products are reviewed and controlled.

Company History

The Company has been producing and selling high quality microsurgical instruments for over 225 years. In 1987 they were acquired by Haag Streit AG of Bern, Switzerland who themselves are manufacturers of world-class ophthalmic instruments. On 01 March 2018 as part of their succession plan, the family of shareholders decided to sell 70% of shares to the Metall Zug Group.

Premises

John Weiss & Son Ltd is located in a commercial site close to the motorway network and main railway line. This site is based in Edinburgh Way, Harlow, Essex, CM20 2TT and is shared by our sister companies Haag Streit UK Ltd, Clement Clarke International Ltd and Clement Clarke Holdings Ltd.

Clement Clarke Holdings

Clement Clarke Holdings Ltd was created in 2012, merging all the support services for the UK group of companies. In conjunction with the organisations it provides full support in order to meet regulatory and business needs.

The services currently provided to John Weiss & Son Ltd are:

• Quality Assurance/Regulatory Affairs.
• Quality Inspection and Control.
• Human Resources.
• Finance.
• Logistics.
• Information Technology.
• Site Services.

The main functions carried by Clement Clarke Holdings personnel with reference to GMP (BS EN ISO 13485:2016) are:
- Regulatory affairs support and advice.
- Maintenance of product technical files.
- Maintenance of the Quality Manual and procedures.
- Patents and trademarks.
- Complaint / vigilance handling.
- Assist in Post Market Surveillance activities.
- Field safety corrective actions (FSCA).
- Product investigations.
- CAPA.
- Internal audits.
- Provision of data for analysis.
- Training.
- Recruitment.
- Maintenance of personnel procedures.
- Health and Safety.
- Infrastructure.
- Cleaning.
- Financial management.
- Reports and analysis for management review and trending.
- Support for design and development.
- Support for barcoding and labelling requirements.

**Distribution Channels**

Product is distributed in the UK market through a direct sales team, NHS supply chain and approved distributors.

Product is distributed throughout overseas markets by approved distributors and importers who are managed by the Export Sales team. Roles and responsibilities of any regulatory correspondents, importers, distributors, or providers of a service are managed through the Supplier approval process and are qualified as suppliers and controlled.

**Reference Documents**

Reference documents are controlled through the External Documents Procedure and verified before use.
Section 3 – Terms and Definitions

Definitions

Definitions have been extracted from the MDR 2017/745

**Medical Device:** any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

**Accessory for a medical device:** An article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

**Manufacturer:** a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

**Authorised representative** Any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to
act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation or jurisdiction's legislation.

**Importer:** Any natural or legal person established within the Union that places a device from another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

**Distributor:** Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

**Economic operator:** A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3);

**Risk management:** Systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

**Quality:** Is a degree to which a set of inherent characteristics fulfils requirements. The term quality is also defined as a totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.

**Product:** Is a result of an interrelated or interacting activity or process.

**Top Management:** Is a person or group of people who direct and control an organisation at the highest level. (See John Weiss & Son Ltd Organisation Chart – located on the front page of the QMS)

**Continual Improvement:** Is a recurring activity to increase the ability to fulfil requirements. The process of establishing objectives and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to corrective action or preventive action.

**Design History File / Technical File:** A compilation of records which describes the design history of a finished device or family of devices.

**Device History Record (DHR):** A compilation of records containing the production history of a finished device or family of devices.

**Device Master Record (DMR):** A compilation of records containing the procedures and specifications for a finished device or family of devices.
Labelling: Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

Lot/Batch: One or more components, finished devices, or products that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality.

Part Specifications (PS): A document that lists items necessary to make, purchase, and inspect a part.

Product Documentation: Document pack that is issued to production that lists everything necessary to make, inspect, and pack a device.

Quality Record: A retained document such as reports concerning inspections, tests, investigations, calibration and qualifications of staff etc.

Section 4 – Quality Management System

Document Hierarchy

Documentation Structure and Change Control

All documentation utilised within the Company related to the management system itself, or to the execution of individual customer contracts is controlled to ensure that it is issued to the
appropriate personnel, under the correct level of authority, is revised and reissued as necessary, and all obsolete versions are removed from the point of use and retained.

The Quality Assurance Manual, procedures and quality plans are maintained by the Managing Director (CCH) and approved by the Managing Director of John Weiss & Son Ltd. This ensures that the appropriate items, are at the correct revision levels and issued to all who need them within the Company.

All shared procedures with sister companies Haag-Streit UK Ltd and Clement Clarke International Ltd will be identified with the use of the John Weiss & Son Ltd Company logo and the CCH logo.

All changes to documents are reviewed and approved by the person responsible for the original issue and, where appropriate, the nature of the change is indicated on the document. Master copies of the revised documents are retained as records of the changes and are renewed as necessary to ensure clarity.

A Device Master Record or Technical File (DMR/TF) is established and maintained and contains product specifications including complete manufacturing and quality assurance procedures for each type of device.

John Weiss & Son Ltd will inform the appropriate regulatory and notified body of any significant changes to the Quality Management System. In addition, John Weiss & Son Ltd will also notify the notified body of all reported incidences and the outcome of its investigations, which fall within the reporting criteria. If the change is to notified body conformity assessments in accordance to MDR 2017/745 Article 53 all aspects and declarations must be adhered to.

In the event that John Weiss & Son Ltd voluntary changes notified body, the actions listed within the MDR 2017/745 Article 58 will need to be adhered to.

**John Weiss & Son Ltd Documentation Structure**

<table>
<thead>
<tr>
<th>Document</th>
<th>Issued under the authority of</th>
<th>Circulation for feedback/approval</th>
<th>Minimum Retention Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality Manual</td>
<td>JW Managing Director</td>
<td>JW Managing Director</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
<tr>
<td>Procedures</td>
<td>JW Managing Director</td>
<td>JW Managing Director</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
<tr>
<td></td>
<td>CCH Managing Director</td>
<td>CCH Managing Director</td>
<td></td>
</tr>
<tr>
<td>Work instructions</td>
<td>JW Managing Director</td>
<td>JW Managing Director</td>
<td>Retained for a minimum of 15 years</td>
</tr>
<tr>
<td></td>
<td>CCH Managing Director</td>
<td>Departmental heads</td>
<td></td>
</tr>
<tr>
<td>Quality Records</td>
<td>JW Managing Director, CCH Managing Director</td>
<td>JW Managing Director, Departmental heads, CCH Managing Director</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
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</tr>
<tr>
<td>Forms</td>
<td>JW Managing Director, CCH Managing Director</td>
<td>JW Managing Director, Departmental heads, CCH Managing Director</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
<tr>
<td>Training aids</td>
<td>Departmental Heads</td>
<td>None</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
<tr>
<td>Validation Documents</td>
<td>Departmental Heads</td>
<td>JW Managing Director, Quality Manager, Technical Operations Manager</td>
<td>Retained for a minimum of 15 years from the last date the last device was manufactured</td>
</tr>
</tbody>
</table>

This retention period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organisation, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements. The lifetime of the device is recorded within the supporting technical file.

**Quality Management System Planning**

An important element of managing the John Weiss & Son Ltd organisation is the implementation and maintenance of an effective quality management system that is designed to enable the organisation to provide medical devices that meet customer and regulatory requirements. John Weiss & Son Ltd can maintain the effectiveness of its established quality management system through a range of activities, including, but not limited to:

- Internal audits.
- Management review.
- Corrective and preventive actions.
- Independent external assessments.
- Post marketing activities.
- Process measurement.
Documentation Requirements

General

Information the organisation requires to ensure the effective planning, operation and control of its processes are documented in a formal quality system and controlled in such a manner as to comply with the appropriate requirement, this includes confidential health information.

The organisation demonstrates its fulfilment of the obligations imposed in (4.1) by ensuring that the products concerned meet the provisions of the standards that apply to them.

The organisation must affix the CE marking accompanied by the identification number of the notified body and draw up a declaration of conformity which must cover the devices manufactured identified by product name, code or other unambiguous reference.

The organisation must prepare and make the following technical documentation available, either through the organisation or its authorised representative, to the national authorities for inspection for a period ending at least 15 years after the last product has been manufactured.

Declaration of Conformity.

- EC type-examination certificates and their additions.
- General description of the product and its intended use(s), including indicating whether the device or any accessories are intended to transport and store substances intended to administer or remove medicines, body liquids or other substances from the body and contain phthalates, carcinogens or other reproductive toxics.
- Design drawings, calculations, diagrams, etc. with necessary explanations.
- Risk analysis results and underlying standard(s).

Documentation Requirements

To define the methods for good documentation practices, completing printed forms legibly and avoiding errors, omissions and ambiguities with respect to written documents.

Quality Manual

The outline of the quality manual is derived from the regulations and standards referenced in section 1 which provides an overview to the elements of the quality system in place to ensure product conformance to specified requirements.

Standard Operating Procedures

Standard Operating Procedures are be written to ensure compliance to applicable Standards, Regulations and Directives.

Procedures will also detail the related processes and where required the interaction between processes.
Control of Documents

Procedures have been developed and are maintained in compliance to the requirements as laid down by Standards and Regulations listed within Section 1. A controlled list is available on the QMS procedure index. A list of controlled documents and quality records shall be maintained, their distribution controlled and reviewed, updated and re-approved as necessary or at a minimum every three (3) years. The documents shall have a control page, be reviewed and approved prior to issue, made available at appropriate locations, subsequent changes reviewed and approved by the same group that performed the original approval.

Documents issued for fabrication and/or assembly of component parts are scanned and then destroyed following completion of the job.

Documents shall reflect, where practical, the date, revision level, and the nature of change and authorisation. Documents of external origin shall be identified, marked as to reference the related internal document(s) and otherwise be treated in the same manner as documents generated internally. Change logs shall be maintained. Derivations from controlled documents shall not be authorised unless specifically approved. To prevent unauthorised copying, copies of controlled documents shall be stamped with an "uncontrolled copy" stamp to readily identify them.

Control of Records

For maximum efficiency, a concerted effort has been made to organise the document flow to accumulate and store related records together in a practical location to facilitate reference and retrieval. Where appropriate, quality records shall provide evidence of conformity to the requirements of the standards specified and remain legible.

Quality records shall be retained for indefinitely. Under no circumstances shall correction fluid be used on any Company document. Line out the error, provide a written justification for the change, initial and date.

Confidential health information is not contained in company records, if any information is inadvertently received it will be handled in accordance to the GDPR Policy and Procedure.

Section 5 - Management Responsibility

Management Commitment

The scope of the quality assurance system encompasses the entire organisation and is mandatory. The baseline specification for the quality assurance system established and
maintained by John Weiss & Son Ltd, reflect the higher of the requirements set forth by the Standards and Regulations within Section 1.

**Customer Focus**

Except for enquiries and orders for a standard product with generic terms, enquiries and orders for non-standard products are reviewed to ensure the requirements are adequately defined, interface with other disciplines as necessary to confirm the Company’s capability to meet the requirements with minimal risk and resolve any differences promptly with the end user.

Increasing pressure from end users for quality products at lower prices coupled with an increase in the number of new manufacturers has made competition very keen. The design criteria must be flexible enough to amortise development costs over several applications. Similarly, the criterion for human resources emphasises versatility over specialisation to achieve the efficiency necessary to respond timely to market demand. As a result, the strategy for securing and maintaining a competitive advantage requires designs based on end user feedback and minimising overhead costs.

For the purposes of export, and upon request of an Authorised Representative, John Weiss & Son Ltd shall issue a Certificate of Free Sales declaring a registered place of business and the device bears the CE mark in accordance to the European Commission.

**Company Quality Policy Statement**

Refer to Appendix A.

**Planning**

**Quality Objectives**

Refer to Appendix B.

**Environmental Policy**

Refer to Appendix C.

**Quality Management System Planning**

The quality system is reviewed and revised to ensure the compliance of products and systems reflect the higher of the requirements set forth by the Standards and Regulations in Section 1.

Continuous improvement meetings take place to review the QMS and identify actions for improvement.
The quality assurance system assures equipment and product protective systems are appropriately classified and where appropriate independently certified and to ensure compliance to all applicable regulatory requirements.

Responsibility, Authority & Communication

Authority

All staff members are allocated with the authority to perform their responsibilities accordingly. The following provides a summary of the principal responsibilities of each job role, and these are clarified in greater detail within the Standard Operating Procedures. All staff share the authority and responsibility of identifying non-compliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence. The Managing Director continually reviews the company’s resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

Irrespective of all other duties the Managing Director (CCH) has the defined authority and responsibility for ensuring that the requirements set out in this manual and procedures are implemented and is also the designated management representative. In the absence of the Managing Director (CCH) the Managing Director (JW) assumes these responsibilities, including reporting on system performance.

Responsibilities

John Weiss and Son Ltd Managing Director

- Is responsible to the CEO of Haag-Streit Holdings AG.
- Is responsible for approving the Quality Manual and the provisions within in respect to the delegation of authority.
- Is responsible for the formulation, planning and implementation of John Weiss & Son Ltd.’s overall Business Strategy.
- Is responsible for the planning and implementation of John Weiss & Son Ltd’s manufacturing strategy, which is part of HSUK’s overall business strategy.
- Is responsible for setting business objectives and communicating them throughout the organisation, the objectives will include the implementation of the quality management system and maintaining its effectiveness.
- Has authority for managing and ensuring that the manufacturing supply chain is effectively planned, co-ordinated, monitored and assessed in order to meet the needs of the customer.
- Has authority for developing and implementing sales objectives that meet the business strategy.
- Is responsible for approving all new design projects and major amendments to existing designs.
• Is responsible for the provision of resources necessary for the implementation of the business objectives.

• Is responsible for carrying out a comprehensive review of the Quality System to ensure its continuing suitability and effectiveness at least once a year. (The review will be documented).

• Is responsible for approving and updating the Company Quality Policy.

• Is responsible for approving & updating the Company Quality Objectives.

• Is responsible for seeing that the instructions that form the basis of our approvals are adhered to in all areas of the Company.

• Is the Director responsible for all Quality functions of the Company.

• Appoints all staff above supervisor level.

• Is responsible for the provision of sufficient staff with the necessary experience to ensure efficient operation in all Departments under their control.

• Is responsible for sales development, home sales, export sales, marketing, order processing and sales forecasting.

• Is responsible for ensuring all customer complaints reported to sales personnel are entered into the complaints system.

• Is responsible for the provision and maintenance of equipment and tools of a suitable type and to ensure they are calibrated as necessary.

Clement Clarke Holdings Ltd Managing Director

Has authority and responsibility for the following list under the appointment of the Managing Director (not exhaustive):

• Is responsible to the CEO of Haag-Streit Holdings AG.

• Is the appointed Management Representative.

• Is also known as Group QA/RA Manager.

• Is the person responsible for regulatory compliance, requirements as stated in MDR 2017/745 Article 15.

• Ensure that quality system requirements are effectively established and effectively maintained.

• Report on the performance of the quality system with executive responsibility for review.

• Review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures.
Ensure that the quality system satisfies all regulatory requirements and the manufacturer's established quality policy and objectives.

Ensures that the Quality Management System clearly defines the quality practices, resources, requirements for quality and activities relevant to devices that are designed and manufactured.

Is responsible for all Regulatory and Quality functions of the Company.

Ensures Quality Management audits are carried out in accordance with audit plan.

Ensures all customer complaints are investigated and appropriate action taken where necessary.

Ensures that all product complaints are reviewed for adverse event reporting to regulatory agencies.

Ensures the Company Quality audit system is effective.

Liaises with outside agencies to maintain existing Company Quality approvals, and negotiates other approvals when required. Ensures the on-going compliance of the Company Quality system with the requirements of EC Directive 93/42/EEC, BS EN ISO 13485:2016, MDSAP and FDA CFR Title 21.

Implementing the Company Quality system and promoting Quality awareness and improvement activities in all Company areas.

Co-ordinates product approval by outside bodies.

Issues a regular report giving general status of quality levels, Customer complaints and progress of particular areas for the Management Review process.

In the event of non-conforming product being produced, or other unsatisfactory conditions exist, has the authority to halt/control production until this condition is corrected.

**Chief Financial Officer / Company Secretary**

Is responsible to the Managing Director (CCH).

Ensures that there are sufficient numbers of staff with the necessary experience to ensure efficient operation in all Departments under his control.
• Is responsible for the provision of equipment of a suitable nature for the work undertaken within budgetary control.

• Is responsible for preparing the Company accounts.

• Is responsible for the efficient running of the Data Processing Department.

Human Resources (HR) Manager

• Is responsible to the Managing Director (CCH)
• To manage and advise on employment law, general health and safety issues, employee relations, policies and procedures, recruitment and training and development.
• Ensure that group policies and procedures follow current legislation.
• Provide general personnel advice and support to the group.

Internal Communication

The Managing Director (JW) is responsible for communicating the organisation’s policy and objectives, and posting it throughout the facility. Similarly, information accumulated from customer feedback, management analysis reports and management review input (including third party audits) shall be communicated within the organisation to achieve the stated objectives demonstrating the organisation’s ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and, enhancing customer satisfaction through effective application and continual improvement of processes within the system.

Management Review

Management review of the suitability and effectiveness of the Quality System take place at least two times per year. During the management meetings actions are allocated and minute to record the development of the Company’s management system.

The objectives of Management Review are:

• To establish that the Quality (Management) System is achieving the expected results and meeting the Company’s requirements, continuing to conform to the Standard, continuing to satisfy the customers’ needs and expectations, and functioning in accordance with the established Operating Procedures.

• To expose irregularities or defects in the System, identify weaknesses and evaluate possible improvements.

• To review the effectiveness of previous corrective actions, and to review the adequacy and suitability of the management system for current and future operations of the Company.
To review any complaints and repair activities received, identify the cause and recommend corrective action if required.

To review the finding of internal / external audits and identify any areas of recurring problems or potential improvements.

To review the reports of nonconforming items and trend information to identify possible improvements.

To review reportable incidents which have been notified to Regulatory Authorities.

To review applicable new and revised regulatory requirements.

Review Labour Standards Assurance Scheme.

Section 6 - Resource Management

Provision of Resources

John Weiss & Son Ltd reviews resources within the management review meetings and during the working year to ensure that adequate resources are in place to deliver the stated objectives and regulatory compliance and react to organisational changes.

Human Resources (HR)

John Weiss & Son Ltd ensures the provision of suitable competent personnel in sufficient quantity to carry out all the functions necessary for the efficient operation of the Company. Awareness and training is provided to ensure all personnel are competent to carry out their duties in maintaining the quality policy of the Company.

The policy of the Company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The Company generally procures and recruits employees capable of meeting the technical, skill, experience and educational requirements of the Company's activities.

All Department heads are responsible for carrying out staff appraisals to identify training needs to ensure that all employees’ allocated specific tasks are suitably qualified and experienced to execute those tasks as documented in the company policy. Once training needs are identified these are documented and passed to the HR department for action. Full records are maintained of all training and review of effectiveness undertaken by employees.

Infrastructure

Premises

JW is located in a building within a planned commercial site close to the motorway network and main line railway. The building consists of a two-story office facility where design, quality, purchasing, stock control, sales, and other support staff are located. Behind this is the logistics area for incoming inspection and warehousing. We also have facilities for meetings, training rooms and site services.
The organisation provides the necessary work space, equipment (both hardware and software) and supporting services to facilitate the execution of the quality management system. All preventative maintenance programs shall comply that recommended by the manufacturer's instruction manual. The appropriate department Head is responsible for highlighting any equipment which requires repair.

**Work Environment**

To maintain awareness of the quality assurance system, minimum standard operating procedures require employees to perform tasks in accordance with drawings and/or procedures and require supervisors to provide a valid example of the quality expected of the employee. Statistical techniques shall be established, maintained and reviewed by management to assure their effectiveness. Further, any indication of non-conformance shall be immediately brought to the attention of the appropriate supervisor(s) and be resolved or removed before resuming the task.

**Section 7 – Product Realisation**

**Planning of Product Realisation**

The organisation has developed and implemented processes needed for product realisation and ensure the compliance of future products with other processes and applicable quality standards.

**Customer Related Processes**

The organisation determines the requirements specified by the customer, including the requirements for delivery and post-delivery activities. Any requirements not stated by the customer but necessary for specified or intended use, will be checked and communicated with the customer before order acceptance. This review is conducted prior to the organisation's commitment to supply a product to the customer to ensure that the organisation has the ability to meet the defined requirements (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders).

All statutory and regulatory requirements related to the product will be reviewed and met.

Records of the results of the review and actions arising from the review are maintained.

Where the customer provides no documented statement of requirement, the customer requirements will be confirmed by the organisation before acceptance. Where product requirements are changed, the organisation ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

The organisation has implemented effective arrangements for communicating with customers in relation to product information, enquiries, contracts or order handling, including amendments, customer feedback, including customer complaints and advisory notices.

The organisation provides an effective website and product catalogue to aid customer order selection.
Agreements shall be put in place with approved Distributers ensuring full understanding of their obligations in regards to complaints, vigilance activities, recalls traceability and corrective and preventative actions to eliminate risks in line with regional regulations.

**Design and Product Development**

All design activities other than Class 1 devices are outsourced to John Weiss & Son Ltd approved organisation(s) and are controlled by the Technical Operations Manager. Technical agreements are raised to ensure that all aspects of the design process are documented and meet regulatory requirements.

Design specifications will be raised and issued by John Weiss & Son Ltd and output data is reviewed with reference to customer/contract requirements, regulatory requirements and design input data.

Design activities are planned by Technical Operations Manager and the status of design project(s) are reviewed by management.

On completion of the design phase of the project, design transfer activities will commence and this will also be controlled via a Technical agreement and action plan.

**Purchasing**

The procurement of materials and services are carried out by the means of purchase orders which are to conform to specified requirements as determined by design and engineering personnel. Deviations require authorisation from the group that issued the original specification.

Suppliers are selected, approved and reviewed in accordance to documented procedures. Each supplier will be risk assessed and periodically reviewed.

Where the design, manufacture and testing of products or key components is carried out by a third party, the quality plan describes the extent of control and methods of monitoring applied to the third party to ensure the products conform to the standards and requirements specified herein.

**Labour Standards Assurance System**

We recognise our obligation to provide our customers with high quality, professional goods and services at a competitive price whilst ensuring that at no point is any person in any part of the supply chain is exploited or treated in any way that breaks any legislation.

We are fully aware of the responsibilities to which we bear to all the parties involved in each of the stages involved in producing our products and have therefore, developed a Labour Standard Assurance System Policy to outline the standards we seek to adhere. We shall
show a preference, where appropriate, to suppliers with higher labour standards. If any supplier is found to breach our LSAS policy the non-conformance will be actioned through the CAPA process.

Our main objective is to become a progressive ethical company.

Approved purchase data and vendors are identified as active in computer files. Incoming components and materials are subject to visual inspection, physical count, physical condition and agreement of company and manufacturer part numbers.

Purchased components are inspected by qualified inspection personnel for compliance with purchasing documents including dimensional drawings. The receipt of said components and materials are verified to and documented. The components and materials are segregated until satisfactory inspection is completed. Manufacturing personnel shall not remove the components or materials until they are inspected and released to production.

Nonconforming material are identified, segregated, and removed to quarantine as soon as possible.

Production and Service

Control of Production and Service Provision

Goods Received Notes (GRN) are generated by the Quality Inspector and inspected and tested in accordance to the inspection level on the ERP system.

Each employee receives specific training with respect to individual procedures. Department heads are responsible for maintaining an appropriate record of this training.

Department heads are authorised to conduct and document at their discretion targeted training reinforcement based on individual instances generated by customer returns and staff requirements.

Installation, maintenance, servicing, repairs, and qualifying procedures have been established for each product. Employees receive specific training with respect to individual procedures.

The Human Resources Department is responsible for maintaining an appropriate record of all training.

Servicing Activities

Procedures are in place ensuring that all servicing activities within JW are carried out and the product is verified to product requirements. Installation, service & repair activities are outsourced to our sister company HSUK. All servicing activities, specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or
safety characteristics or its intended purpose, shall ensure that the item does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available for the competent authorities of the Member States.

JW will not authorise to replace a part or component of a device that significantly changes the performance or safety characteristics or intended purpose of the device.

Outputs from the servicing process are reviewed at the Management Review.

Validation of Processes for Production and Service Provision

Validation of processes for production and service provision is carried out in accordance with regulatory requirements. Procedures have been put in place to ensure that all new or significantly modified manufacturing, service processes or addition of new plant are validated against the required performance specification to demonstrate that they have the ability to achieve planned results.

Identification and Traceability

The organisation identifies the product by suitable means throughout product realisation, and has establish documented procedures for such product identification. The organisation has established documented procedures to ensure that medical devices returned to the organisation are identified and distinguished from conforming product.

The organisation has established documented procedures for traceability. The procedures define the extent of product traceability and the records required. For all active medical devices, the organisation has implemented processes so that all unique identification (serial numbers) are recorded and retained.

The batch identification and traceability of all parts are recorded and maintained within the organisation ERP system.

The organisation has full traceability from raw material to end user.

Customer Property

All customer property, whether items for repair or free issue material, will be handled, segregated and maintained in accordance with regulation requirements and where required communication with the customer will take place before product disposition is carried out.

Preservation of Product

The organisation’s processes have been designed to preserve the conformity of the product and related components during internal processing and delivery to the intended destination. Preservation shall include but is not limited to identification, handling, packaging, storage and protection. The identification of materials/equipment, where it is not obvious, is confirmed by the presence of a manufacturers/suppliers part number or description label, or other marking for each item. The identification of the item may be on the packaging or on the item itself, and this
identification remains in place for as long as possible, provided it does not hamper effective use of the item. Materials and consumables are not identified by the Company where they are obvious to a trained/experienced employee, however, should a risk of misinterpretation exist between two or more types of material these will be marked in a suitable manner to ensure that no ambiguity exists.

Materials and goods received, whether the property of the company or others, will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer, or disposed of to a third party. The objective is to prevent deterioration and damage whilst in storage, or in the process of transportation, installation, commission.

Control of Monitoring and Measuring Devices

The Quality Control Manager (CCH) in liaison with the design authority is responsible for determining the appropriate inspection and test equipment necessary to ensure product quality.

Further, procedures have been developed to ensure the equipment is controlled, calibrated as necessary, maintained, and that the intended users are trained to use the equipment correctly. In the event that equipment is found to be out of tolerance upon routine calibration or recommended checks a documented formal review of the effect of the out of tolerance condition on product shipped, completed inventory and work in process are conducted.

Section 8 - Measurement, Analysis and Improvement

General

The organisation has implemented appropriate methods, including statistical techniques, for the monitoring, measurement, analysis and improvements needed to demonstrate conformity of the product, ensure conformity of the quality management system and to continually improve the effectiveness of the quality management system.

Feedback

As a means of assessing the performance of the quality management system, the organisation monitors information to determine whether the organisation has met customer requirements, this will be carried out via customer feedback mechanisms e.g. Questionnaires, verbal, exhibitions and complaint analysis.

Complaints handling is documented, reviewed and maintained in accordance to regulatory requirements.

Internal Audit

Internal audits of the Quality System are undertaken at least once per 18 months to confirm that the function concerned is adhering to the Company's Procedures. A comprehensive Audit Programme is compiled at least a year in advance however, should particular needs be identified the frequency of audit may be increased at the discretion of the CCH Managing Director. Audits are undertaken by auditors who are trained in auditing and not directly responsible for the functions being audited. Non-conformance observed is brought to the
attention of the person responsible, and is recorded, documented and subject to timely corrective action to ensure full rectification.

**Monitoring and Measurement of Processes**

All productive work is planned and undertaken in accordance with the Company's Procedures, and any specific documents agreed for individual contracts.

Where it has been chosen to outsource any processes that affect product conformity, John Weiss & Son Ltd will ensure control over these processes by means of a written contract. This contract will define responsibilities, controls, key performance indicators, and outline the procedure for communication between parties and will be signed by both parties. The contract does not absolve the organisation of the responsibility of conformity to the customer, statutory and regulatory requirements.

Where language translations are required for labelling, instructions for use etc., validation will be carried out by the country specific distributor before acceptance.

**Monitoring and Measurement of Product**

Inspection and testing is carried out on completion of installation and maintenance activities, with results being documented. Should items not be acceptable against the agreed contract criteria they will be repaired, replaced or identified for a subsequent evaluation and decision.

All repaired items are subject to a re-inspection to ensure acceptability. All stores areas are maintained as secure as practical. All items received by the Company are identified and verified in accordance with the requirements of the Delivery Note and Purchase Order, and are inspected for correct identity, quantity and any signs of damage. All goods received are documented and, in the event of non-conformance, the items are placed in a reject area or labelled to ensure identification.

**Non-Conforming Items, Corrective and Preventive Actions**

Once non-conforming items have been noticed they are identified by location, associated documents, or specific markings to prevent their inadvertent use. All non-conforming items and customer complaints are subject to review and rectification by nominated personnel. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated, documented, and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

**Analysis of Data**

The organisation collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and identify opportunities where improvements can be made. Sources include data generated by compliance records, processes and other relevant sources.
Summary feedback from devices in the postproduction phase are reviewed during Management Review meetings and where appropriate the recording of any implemented corrective action, including notifying the competent authorities of any malfunction or deterioration in the performance of a device or inadequacy in the instructions for use which might lead to or might have led to the death of a patient or serious deterioration in the state of health or a systematic recall of devices.

**Improvement**

**General**

The objective of the quality assurance system is two-fold: a) to demonstrate the organisation’s ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and, b) aims to enhance customer satisfaction through effective application and continual improvement of processes within the system. Information accumulated from customer feedback, management analysis reports and management review input (including third party audits) are communicated within the organisation to achieve the stated objectives - demonstrating the organisation’s ability to consistently provide product and the assurance of conformity to applicable customer and regulatory requirements, and enhancing customer satisfaction through effective application and continual improvement of processes within the system.

**Corrective Action**

Use of corrective action process is not limited to deviations from procedures, nonconforming product or internal quality audits. Opportunities for improvement are accorded the same degree of investigative analysis, documentation, determination and implementation of conclusions. Where deemed necessary by feedback from the marketplace, competent authorities, customer complaints or the assessment of returned material, procedures have been established to provide customers with an advisory notice or conduct a product recall in accordance with MEDDEV guidance.

Formal CAPA investigation requests are limited to significant events which via a risk score require CAPA actions. The appropriate department heads verify and sign off the CAPA form so that the change is effective.

The appropriate Department heads are authorised to designate, approve, and implement changes including but not limited to clarifications, modifications for special one of a kind orders, typographical errors, etc. based on informal discussions, sketches, red line notes, etc.

Reporting of serious incidents and field safety corrective actions, including recalls procedures are established; with respect to relevant competent authorities and what to report, format, content and timescales.
Preventive Action

John Weiss & Son Ltd adopts an 8D process to support the identification of root cause(s) and instigates actions to eliminate potential non-conformities. The outputs are documented within the CAPA system and reviewed.
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<tr>
<th>Prepared by:</th>
<th>Reviewed By:</th>
<th>Approved by:</th>
<th>Date</th>
<th>Revision</th>
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<tr>
<td>K. Osborne</td>
<td>G. Ostacchini</td>
<td>M. Bench</td>
<td>12 Apr 2016</td>
<td>22</td>
<td>Update of all procedures. Inclusion of Labour Standards, Update to include International Sales Manager and removal of International Product Manager. Product Development relocated to Managing Director.</td>
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<tr>
<td>K. Osborne</td>
<td>G. Ostacchini</td>
<td>M. Bench</td>
<td>30 Apr 2018</td>
<td>23</td>
<td>Removal of procedure numbers, addition of explanation of procedure index. Update to Standards and clarity on which specific version. Inclusion of BS EN ISO 13485:2016. Inclusion of Virtual Manufacturer requirements within scope. Non applicability’s updated to 2016 standard. Inclusion of Confidential health information (GDPR), addition of 7.5.4 Servicing activities., Update to operations manager responsibilities</td>
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<tr>
<td>T. Whay</td>
<td>G. Ostacchini</td>
<td>D. Johnson</td>
<td>26 Jul 2019</td>
<td>25</td>
<td>Updates to all sections to reflect updated regulatory requirements, document now matches the HSUK Quality Manual.</td>
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