medi UK Ltd is committed to being a leader in the sales and marketing of orthopaedic, medical compression garments and associated devices, and the Lifestyle range of CEP.

medi UK Ltd transitioned to ISO9001:2015 in February 2018 and is committed to maintaining this standard:

- Senior management shall show leadership by taking full accountability for the Quality Management System; they shall determine the context of the organisation, the strategic direction, the interested parties and the risks and opportunities that need to be addressed.

- The Quality Policy, Objectives, Processes and all other requirements of the Quality Management System shall be determined, recorded and communicated throughout the company; when necessary they shall be communicated to external providers and interested parties.

- Quality Objectives are confirmed as follows:-
  - To increase sales into all sectors of the UK market
  - To have good employee relationships and maintain good working practices through training and development
  - To meet our customers' expectations of our products and services, and to maintain high levels of satisfaction by acting on feedback from our customers

- Continuing compliance of the Quality Management System to the ISO9001:2015 standard shall be sought through an annual program of internal audits; the results of which shall be used by Top Management to continuously improve the products and services, quality policy, objectives, context and strategic direction of the organisation.

- The use of the process approach and risk-based thinking shall be promoted within the organisation.

- All organisational knowledge required for the ongoing continuity of medi UK's processes, goods and services, is to be documented and controlled by means of a quality procedure or written instructions; this knowledge is to be made readily available within the organisation.

- The organisation shall provide training and support in order to meet the roles and responsibilities defined in the QMS.

- All Customer, statutory and regulatory requirements are to be determined, understood and consistently met; all goods and services provided to our customers shall be fit for purpose, cost effective and delivered on time.

- The level of Customer satisfaction shall be assessed and reviewed on an ongoing basis; any subsequent findings shall be used to improve the Quality Management System, Quality Policy and Objectives.

- The organisation shall continue to establish relationships with its customers, external providers and interested parties.

Signed: Ian Grant, Managing Director, medi UK Ltd

Date: 2nd Sept 2019

Review due on: July 2020

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4. CONTEXT OF THE ORGANISATION

4.1 Understanding the organisation and its context

[a] Background
In 1984 a Partnership was formed between STD Pharmaceutical Products and Weihermuller Voigtmann (later to be known as medi Bayreuth). This Partnership was known as medi UK and became incorporated as medi UK Limited in 1987. The object of forming the Company was to provide a distribution outlet in the UK for products manufactured by the German Plant of Weco Weihermuller Voigtmann. In 2010 medi International bought the STD shareholding in medi UK Ltd allowing medi GmbH to continue investment in medi UK Ltd whilst STD continued to perform the logistics, warehousing, and administration for medi UK Ltd. Following the de-merger of STD Pharmaceutical Products Ltd on 1st July 2019 all service provided in the service agreement by STD were novated to the new company Limbco Ltd.

[b] Products
The products supplied by medi Bayreuth and offered in the UK, include the RAL quality mediven range for lymphatic and venous conditions, in addition to the traditional elastic compression hose/ery made to the British Standard specification 40. They also provide a range of Anti Embolism Stockings, orthopaedic products and the Lifestyle range, including CEP. The company also markets the “Hereford Collar” which is manufactured by Moorland Manufacturing in the UK. The Juxta range of products manufactured by medi Bayreuth and the Mesi ABPI device manufactured by Mesi in Slovenia have been added to the UK portfolio to compete in the Woundcare market.
New orthopaedic products JAS, EMPI and Gamechanger have been added to the product range.

[c] Outlets
The company principally sells to the NHS through hospitals, clinics and more recently through the network of pharmacies as the community business develops. The Lifestyle range of CEP are sold via the webshop or directly to retail outlets.

4.1.1 Internal and External Influences and Interested Parties have been considered and are monitored through their own documented system and are updated on a regular basis. Any changes are entered into the change management system and are updated and monitored regularly. Risk factors have been set in its own documented system and are monitored and updated regularly.

4.2 Understanding the needs and expectations of interested parties
Interested parties and internal and external influences have been considered and are monitored through the Interested Parties, Internal and External Influences system which is monitored and updated on a regular basis.

4.3 Determining the scope of the quality management system
The Company’s ISO 9001: 2015 quality management system applies to the sales and marketing for a range of orthopaedic, medical compression garments and the Lifestyle range of CEP. The company Mission / Vision Statement is below:

Mission Statement / Vision
Our aim is to bring long term benefits to our customers, staff and our shareholders by sustainable growth in sales of products that improve the quality of life of users of Vascular, Orthopaedic and Lifestyle products

4.4 Quality management system and its processes
The Company will establish, document, implement and maintain a quality management system based upon analysis and improvement in accordance with the requirements of this

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International Standard. Where processes are outsourced the type and extent of control to be applied will be defined in the quality management system.

4.4.2 The company will maintain documented information to support its operations and will retain this information for future reference

5. LEADERSHIP
5.1. General
The Managing Director will demonstrate leadership and commitment to the Quality Management System by:

[a] a business plan will be prepared yearly to communicate the strategic direction of the business which is compatible with the Quality Management System
[b] ensuring the availability of resources
[c] supporting staff so they can contribute to the effective working of the Quality Management System
[d] improvements to be monitored through the Change Control System

The Managing Director is ultimately responsible for the Company's Quality Policy and totally committed to the Company's Documented System to ISO 9001: 2015. He will ensure that there are adequate resources to develop, implement and continually improve the documented quality system to achieve and maintain high levels of customer satisfaction.

5.1.2. Customer Focus
The Managing Director will ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction.

[a] customer requirements as well as statutory and regulatory requirements
[b] continually monitor customer satisfaction through the monitoring of complaints and also the completion of the Customer Satisfaction Survey every 2-3 years.

5.2 Policy
5.2.1 Establishing the Quality Policy
The policy is in place and is authorised by the Managing Director. This is communicated internally through quality assurance training which also includes objectives. This also includes the mission statement and policy statement in the employee handbook. Policy has been reviewed and changes have been made to include interested parties and requirements.

5.2.2 Communicating the Quality Policy
Quality Policy will be communicated in both paper copy held in the office and in electronic format on the company computer system.

5.3 Organisational roles, responsibilities and authorities
The organisation shall provide training and support in order to meet the roles and responsibilities defined in the QMS.

6. PLANNING
6.1 Actions to address risks and opportunities
The internal and external influences and needs and expectations of interested parties have been established and contain an evaluation of risk, where improvements have been identified the management of change process ensures effective process improvements.

6.2 Quality objectives and planning to achieve them
The Company Quality Policy contains quality objective which are appropriate to the business and are understood and supported by each employee. The outcome is to achieve
a quality service to our customers who in turn provide our products to the end user. To provide such a service our systems are audited in accordance with our quality policy to monitor and reduce customer complaints, maximise employee satisfaction in all aspect of our operation and to ensure customer satisfaction at all times. Appraisal of our Quality Objectives and outcomes are reviewed during the management review. These objectives can be confirmed as:

- To increase sales into all sectors of the UK market
- To have good employee relationships and maintain good working practices through training and development
- To meet our customers' expectations of our products and services, and to maintain high levels of satisfaction by acting on feed-back from our customers.

6.3. Planning of changes
The change management system has been created to monitor changes within the organisation and covers the stages of change as identified within the clause. The document also includes the identification of interested parties, internal and external influences which may be affected by the change.

7. SUPPORT
7.1 Resources
7.1.1 General
The Company will determine and provide the resources needed to:

[a] Implement and maintain the quality management system and continually improve its effectiveness.
[b] Enhance customer satisfaction by meeting customer requirements.

7.1.2 People
The Company will ensure that personnel performing work affecting conformity to product requirements are competent on the basis of appropriate education, training, skills and experience.

7.1.3 Infrastructure
The Company will determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

[a] Buildings, workspace and associated utilities,
[b] Process equipment (both hardware and software).
[c] Supporting services (such as transport or communication or information systems).

7.1.4 Environment for the operation of processes
The Company will determine and manage the work environment needed to achieve conformity to product requirements.

7.1.5 Monitoring and measuring resources
The Company will apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods will demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action will be taken, as appropriate.

7.1.6 Organisational knowledge
Staff turnover is very low. Manning levels are reviewed regularly. Skill levels vary throughout the operational process and an ongoing review of these is carried out with our external provider who provides outsourced processes at the same site at monthly meetings and ad hoc meetings when necessary. A multi-skilled approach is taken with most training being on the job with external training resourced as needed

7.2 Competence
The Company will:
[a] Determine necessary competence for personnel performing work affecting conformity to product requirements.
[b] Where applicable, provide training or take other actions to achieve necessary competence.
[c] Evaluate the effectiveness of the actions taken,
[d] Ensure people awareness to relevance and importance of achievement of quality objectives.
[e] Maintain appropriate records of education, training, skills and experience

7.3 Awareness
The employee handbook contains the Quality Policy and all employees sign to say they have received this and have an understanding. KPI’s are posted and communicated at monthly management meetings, communications are in place for nonconforming outputs.

7.4 Communication
7.4.1 Communication forms part of the documents that list internal and external influences, interested parties and change control.
7.4.2 Effective arrangements for communicating with customers will cover: -
[a] Product information,
[b] Enquiries, contracts or order handling, including amendments.
[c] Customer feedback, including customer complaints.

7.5 Documented information
7.5.1 General
This Quality Policy Manual (First Tier of Documented Quality System) will include: -
[a] Documented statements of a quality policy and quality objectives.
[b] Clauses of ISO9001 / 2015
[c] Documented procedures and records required by ISO 9001: 2015
[d] Documents including records determined by the Company to be necessary to ensure the effective planning, operation and control of its processes.
[f] The scope of the quality management system.

7.5.2 Creating and updating
A document control process map is in place which includes customer documents, a register of procedures and forms is kept with retention control in place. Issue is authorised by senior management who are involved in all changes. The system has 1 manual as below: -
1. External Provider - Limbco Ltd (formerly STD Pharmaceutical Ltd) – who provide outsourced processes at the same site
A copy of the manual is available on medi UK’s Sharepoint for senior management and staff to access.

7.5.3 Control of documented information
The company will establish a process for storage, protection, retrieval, retention and disposition of records to provide evidence of conformity to requirements and effective operation of the quality management system. Such records shall remain legible, readily identifiable and retrievable.

8. OPERATIONS
8.1 Operational planning and control
All activities have process maps in place. Most products are sourced from the parent company in Germany and there are no manufacturing processes at the UK Plough Lane site. We purchase another product being the Hereford Collar from Moorland Manufacturing at another location. We also source a number of orthopaedic products from other companies based in the USA
Sales and marketing for the business are controlled by medi UK Ltd. The purchasing of stock, storage and distribution is carried out through an external provider. A good inwards process is established, receipt of product, storage and distribution are carried out by the external provided at

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5
our shared location. Trained staff in the warehouse areas ensure compliance to requirements of purchase orders.

8.2 Requirements for products and services
8.2.1 Customer Communications
   Effective arrangements for communicating with customers will cover: -
   [a] Product information,
   [b] Enquiries, contracts or order handling, including amendments.
   [c] Customer feedback, including customer complaints.

8.2.2 Determining the requirements for products and services
The requirements for products and services offered to customers show any applicable statutory
and regulatory requirements and meet any claims for the products and services it offers.

8.2.3 Review of Requirements Related to the Product
The external provider based on the same site manages order input and complaints and this is fed
back to medi UK, they also manage customer returns under the controlled process which has
been agreed through a contractual agreement between the two Managing Directors.

8.2.4 Changes to requirements for products and services
The Managing Director will ensure that relevant documented information is amended, and that
relevant persons are made aware of the changed requirements, when the requirements for
products and services are changed.

8.3 Design and development of products and services
This clause is excluded from the documented quality system since the Company does not design
its products nor offer any design service. Design is a parent company responsibility.

8.4 Control of externally provided processes, products and services
8.4.1 General
The organisation has only a sales and marketing activity and therefore the stock, management,
order input, sourcing, receipt, storage and distribution is outsourced to the external provider at
the shared location
8.4.2 Type and extent of control
Continuous monitoring and monthly performance meetings with external provider.
8.4.3 Information for external providers
The stock management, order input, sourcing, receipt, storage and distribution is outsourced at
the shared location by the external provider. Agreed controls are in place and are verified on a
continuous monitoring and monthly performance meetings.

8.5 Production and service provision
8.5.1 Control of production and service provision
There is no production on site all production takes place either at parent company site or at other
product site of another company
8.5.2 Identification and traceability
There is a requirement for traceability of the Mesd machine, all other products are identified by
product code.
8.5.3 Property belonging to customers or external providers
The company will exercise care with customer property while it is under our control. The
Company will identify, verify, protect and safeguard customer property provided for use or
incorporation into the product.
8.5.4 Preservation
The Company will exercise care with customer property while it is under our control. If any
customer property is lost, damaged or otherwise found unsuitable for use, the Company will
report this to the customer and maintain records.
8.5.5 Post-delivery activities

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Product from parent company is identified by the product code and there is no requirement for traceability. All other products are identified by product code and there is no requirement for traceability.

Traceability Mesi Machine – serial numbers of machines are logged in and out on Greentree, and serials numbers are also logged in Prospect so notes can be made on each machine should they be required.

[a] there are no statutory and regulatory requirements  
[b] there are no potential undesired consequences associated with the products  
[c] the intended lifetime of the products is between 3-12 months depending on individual product, Mesi machine intended lifetime is 5 years  
[d] Ensuring the promotion of awareness of customer requirements throughout the Company through communication with each other and customers  
[e] customer feedback is continually monitored and a Customer Satisfaction Survey is carried out every few years.

8.5.6 Control of changes
Changes are controlled by the Change Management/Control system which is monitored and updated on a regular basis.

8.6 Release of products and services
Final inspection is in place through the external provider for product release through the external provider’s warehouse and a bar code checking process.

8.7 Control of nonconforming outputs
The Company will ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Where applicable by the following methods:

[a] Taking action to eliminate the detected nonconformity.  
[b] Authorising its use, release or acceptance under concession by relevant authority or the customer.  
[c] taking action to preclude its original intended use or application.  
[d] By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.  
[e] When corrected it shall be subject to re-verification to demonstrate conformity to requirements.  
[f] Records of nonconformities and any subsequent actions taken, including concessions obtained.

9. PERFORMANCE EVALUATION
9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
The Company will plan and implement the monitoring, measurement, analysis and improvement processes needed to:

[a] Demonstrate conformity to product requirements  
[b] Ensure conformity of the quality management system  
[c] Continually improve the effectiveness of the quality management system

This will include determination of applicable methods, including statistical techniques, and the extent of their use.

9.1.2 Customer Satisfaction
This may include outcomes of customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, repeat business and compliments etc.
9.1.3 Analysis and evaluation
The Company will determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This will include:

[a] Customer satisfaction.
[b] Conformity to product requirements.
[c] Characteristics and trends of processes and products including opportunities for preventive action.
[d] Suppliers.

9.2 Internal Audit
Internal audits will be conducted to ensure the requirements of both ISO9001:2015 and the Company's own quality management system requirements are met. This will include:

[a] Audit schedule, scope, frequency, methods, records and reporting results.
[b] Status and importance of the processes and areas to be audited.
[c] Selection of auditors and conduct of audits that ensures objectivity and impartiality of audit process.
[d] Follow up action to address any non-compliances reported.
[f] Managers responsible for areas audited must ensure and necessary corrections and corrective actions are taken without due delay to eliminate detected nonconformities and their causes.

9.3 Management Review
9.3.1 General
The Managing Director will review the quality management system yearly to ensure its continuing suitability, adequacy and effectiveness.

9.3.2 Management Review inputs
Input to management review will follow a defined Agenda covering documented quality system.

9.3.3 Management Review outputs
Output from the management review will include any decisions and actions related to:

[a] Improvement of the effectiveness of the quality management system and its processes.
[b] Improvement of product related to customer requirements.
[c] Resourcing needs.

10. IMPROVEMENT
10.1 General
Monthly Management meetings review performance against requirements such as KPI's, undesired effects are reviewed as outputs of internal nonconformities, reflects as highlighted by process failures and outcome of customer complaints. Improvement requirements are made through the management of change document.

10.2 Nonconformity and corrective action
The Company will continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

10.3 Continual improvement
The Company will continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
AMENDMENT PROCEDURE
In the event of an amendment being carried out to any section of this Policy Manual, the Issue Status of the whole of that page will be changed. Amendments will be carried out as follows:-

[a]  Text revised to accommodate the change.
[b]  Issue Number on the amended page updated accordingly.
[d]  Details of change recorded on Amendment Record.
[e]  Obsolete pages withdrawn.
All amendments must be signed and dated

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<tr>
<td>06/07/09</td>
<td>Whole Document</td>
<td>1 - 2</td>
<td>The Quality Policy Manual has been completely re-written to address the changes in the revised ISO9001/2008 standard</td>
<td>Carol Manning</td>
<td>06/07/09</td>
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<tr>
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<td>Whole Document</td>
<td>2 - 3</td>
<td>Amend to show change in ownership of company. Also amend 3.3 Outlets to more correctly show the outlets being used since the company has put more products onto the Drug Tariff</td>
<td>Carol Manning</td>
<td>27/09/10</td>
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| 1/05/11  | Whole Document  | 3 - 4                  | Amendment to show change in Directors.
1.2 amended to more correctly show the quality objectives of the company.
3.2 amended to more correctly show the products the company sells | Carol Manning       | 01/05/11|
| 2/09/16  | Whole Document  | 4-5                    | Show Quality Objectives more succinctly Add new product range and outlets                                                                                                                                  | Carol Manning       | 2/09/16 |
| 22/12/16 | Whole Document  | 5-6                    | Update of Quality Policy Manual to new standard ISO 9001: 2015                                                                                                                                               | Carol Manning       | 05/01/17|
| 19/12/17 | Whole Document  | 6-7                    | Minor amends to layout, spelling and index                                                                                                                                                                   | Carol Manning       | 19/12/17|
| 30/07/18 | Whole Document  | 7-8                    | Add new orthopaedic products. Add 8.5.2 – 8.5.4 Identification and traceability. Add 8.5.5 Post Delivery [c] add lifetime of Mesi machine                                                                 | Carol Manning       | 30/07/18|
| 15/08/19 | Whole Document  | 8-9                    | Review of document. 4.1 Background - Change to outsourced supplier from STD to Limbco Ltd.                                                                                                                 | Carol Manning       | 15/08/19|
| 4.1 [b] Products – change Slovakia to Slovenia |
| 8.5.5 Post-delivery activities – Traceability, add Mesi machine details |
| 7.5.2 Creating and Updating - update to manual availability |
| 8.1. Operational planning and control – Ortho products add “based in USA” |
| Minor layout changes |