

QUALITY SYSTEM INFORMATION

Company: **HMC Premedical S.p.A.**
Accredited Certification Body: **IMQ S.p.A.**
International Standard: **ISO 13485:2016**
Certificate number: **9124.HMCP**
First Issue: **2014-04-19**
Current Issue: **2021-05-13**
Expiry: **2023-04-17**

Certification: **CE Certificate according to Directive 93/42/EEC and amendments**
Certificate number: **1668/MDD**
Class of Medical Devices: **Class IIa - IIb**
Issue: **2014-04-22**
Update: **2021-05-07**
Expiry: **2024-04-18**

Certification: **CE Certificate according to Directive 93/42/EEC and amendments**
Certificate number: **1669/MDD**
Class of Medical Devices: **Class I sterile**
Issue: **2014-04-22**
Update: **2021-05-07**
Expiry: **2024-04-18**

- *Standard Operating Procedure and Work Instructions relating to the following:*

- Quality Management System
- Management Responsibility
- Resources Management
- Product Development
- Product Realization and storage
- Product Release
- Measurement, Analysis & Improvement
- Critical Process Validation
- Purchasing
- Customer Orders Review
- Complaint, Non Conformities and CAPA management
- Traceability system
- Sterilization
- Change Control
- Vigilance System, PMS, PMCF, Clinical Evaluation

- *Production in environmental controlled areas:*

ISO 8 Clean room for Moulding, Extrusion and Automatic Assembling
ISO 8 Clean room for Manual Assembling and Sterile Packaging

- *Certificate Of Conformity supplied together with products at each delivery*

QUALITY CONTROL INFORMATION

- Standard Operating Procedures and Work Instructions for Quality Controls on products in every phase of product realization:

- Incoming raw materials and components
- Molding process
- Extrusion process
- Automatic Assembling process
- Manual Assembling process
- In Bulk and Sterile Packaging

- Statistical Quality Control System according to ISO 2859-1 requirements. Standard plan:

Sampling Plan: **Single Sampling Plan**

Inspection: **Normal**

Level: **I**

AQL (moulded components): **0,15 (Critical) ; 1 (Major)**

AQL (tubes): **0,15**

AQL (assembled and finished products): **0,25**

- In process controls on each machine

- Possibility to apply different plans according to customer specification

- Inspections on products:

- Visual Inspections
- Dimensional Inspections
- Technical Inspections: Tensile test, Compression test, Pressure test, Leakage test, etc.

- Calibrated Testing Equipment:

- Three-Axis Optical Measuring System with Renishaw Touch Probe
- Profile Projectors
- On line laser for tubes diameter measuring
- Force testing equipment (Traction and Compression)
- Peel Force testing equipment
- Leakage pressure equipment up to 8 bar
- Digital calipers, micrometers, cylindrical pins, Luer gauges according to ISO 80369-7, ENFit gauges according to ISO 80369-3