

EU Declaration of Conformity Regarding Medical Device Regulation(EU)2017/745

Manufacturer

Company: Hubei MeterOmega Technology LTD

Address: 1F&2F, Building 3, Biomedical Industrial Park, Jianqiu 5th Road, Duodao District, 448000, Jingmen City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000016732

European Representative

Company: Humiss Beratung GmbH

Address: Gneisenaustraße 8, 40477 Düsseldorf, GERMANY

SRN: DE-AR-000023447

Product

Name: Arterial Hemostasis Compressor

Models: N, NP, TP, TS, NWXL, PWXL

MDN 1204, MDS 1005, MDT 2002, MDT 2004, MDT 2008, MDT 2011

EMDN code: M040599

Product Name	Model	Basic UDI-DI
Arterial Hemostasis Compressor	N, NP, TP	697461717301LK
	TS	697461717302LM
	NWXL, PWXL	697461717303LP

Classification: Class Is

Rules: Rule 4, main paragraph + 1st indent

Conformity assessment procedure: Part A of Annex XI

Notified Body: TÜV SÜD Product Service GmbH

Address: Ridlerstraße 65 • 80339 München • Germany

CE 0123

EC certificate No.: G26 119776 0004 Rev. 00

Issue date: 2025-06-23

Valid until: 2030-06-22

Manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of MDR Regulation(EU)2017/745, and its transposition into national laws. The products comply with the General Safety and Performance Requirements of Annex I, further applicable standards/common specifications and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

The above referenced products will bear the CE mark as below.



We confirm our product meets the requirements of Medical Device Regulation (EU)2017/745 and the following harmonized standards/common specifications.

No.	Standard No.	Version	Title
1	Regulation(EU) 2017/745	2017	Medical Device Regulation
2	EN ISO 13486	2016/A11 :2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
3	EN ISO 14971	2019/A11 :2021	Medical Device - Application of Risk Management in Medical Device
4	EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied General requirements.
5	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer
6	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
8	EN ISO 10993-7	2008/A1: 2022	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residual
9	EN ISO 10993-10	2023	Biological Evaluation of Medical Device - Part 10: Tests for skin sensitization
10	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
11	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
12	EN ISO 10993-18	2020	Biological evaluation of medical devices - Part 18: Chemical characterization of materials
13	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
14	EN ISO 11135	2014/A1: 2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
15	EN ISO 11737-1	2018/A1: 2021	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
16	EN ISO 11737-2	2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
17	EN 556-1	2001/AC: 2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
18	European Pharmacopoeia	/	/
19	EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
20	EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing

			and assembly processes (ISO 11607-2:2019)
21	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
22	ASTM F1886/F1886M	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
23	ASTM F88/F88M	2015	Standard Test for Seal Strength of Flexible Barrier Materials1This standard is issued under the fixed designation
24	ASTM F1929	2015	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
25	ASTM F1608	2016	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)
26	ASTM F1140/F1140M	2013	Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages
27	DIN 58953-6	2016	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
28	ASTM D4169	2016	Standard Practice for Performance Testing of Shipping Containers and Systems
29	MDCG 2020-5	2020	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
30	MEDDEV 2.7.1 rev.4	2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
31	MEDDEV 2.12-1 rev.8	/	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
32	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers

Name and Signature: Coco Ke

Position: PRRC

coco ke

Date and Place: June 23rd, 2025, Hubei

