

EC-Certificate of Conformity

The Notified Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith confirms that the company

Heinz Herenz Medizinalbedarf GmbH
Rudorffweg 10
21031 Hamburg
Germany

With its facility as per attachment 1

has introduced, applies and maintains a quality assurance system
for the products / product categories:

- **Transfusion sets**
- **3-way-stopcocks**
- **Digital thermometers**

The compliance of the quality assurance system with the below mentioned requirements of the
Council Directive 93/42/EEC was verified by an audit:

Annex V

This certification is subject to surveillance by MEDCERT.

This certificate is valid until: 27 April 2024

Report No.: 1249FS22F
Process No.: QS-1249
Certificate No.: 1249GB414190513

Hamburg, 13 May 2019



MEDCERT Certification Body
(Markus Bianchi)

MEDCERT Identification No.: 0482



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-237.10.15

**Attachment 1
EC-Certificate of Conformity
QS - 1249**

This Attachment is valid only in connection with certificate No.: 1249GB414190513

**Heinz Herenz Medizinalbedarf GmbH
Osterrade 54
21031 Hamburg
Germany**

Hamburg, 13 May 2019



MEDCERT Certification Body
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Certificate

The Certification Body

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany

herewith certifies that the company

Heinz Herenz Medizinalbedarf GmbH
Rudorffweg 10
21031 Hamburg
Germany

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

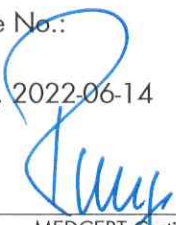
EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: 2022-06-14
Expiry date: 2025-04-27

Report No.: 1249FS25F
Procedure No.: QS – 1249
Certificate No.: 1249GB445220614

Hamburg, 2022-06-14



MEDCERT Certification Body
Lorenz Runge

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body
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Appendix of certificate

Procedure No.: QS – 1249
Certificate No.: 1249GB445220614

Activities and products/services in the scope of certification

Design, manufacture, final inspection and distribution of

- Intravenous cannulas
- Blood- and allergy lancets
- Scalpel blades
- Single use scalpels
- Stitch cutters
- Covers for sonography sondes
- ECG-electrodes

Distribution of

- Blood bags
- Medicine cups
- Sterile single use forceps
- Emergency cold wraps

Manufacture, final inspection and distribution of

- 3-way-stopcocks
- Transfusion sets
- Digital thermometers
- Instruments
- Tourniquets
- Ultrasound gel
- Gynaecological accessories
- Alcohol swabs
- Protective clothes
- Haemacytometer
- Disposables
- Urine bottles and cups
- Brushes for gynaecological sample taking
- Disposable razors
- Blood collection tubes
- Capillary tubes
- Plastic containers
- Cold-/hot wrapsp
- Stethoscopes
- Aneroid sphygmomanometers
- Sterile and non-sterile tongue depressors
- Sterile cotton swabs
- Sterile bacterial sample collecting sets
- Sterile urine bags
- Sterile surgical covers

This appendix is integral part of the above-referenced certificate.
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Appendix of certificate

Procedure No.: QS – 1249
Certificate No.: 1249GB445220614

Locations in the scope of certification

Heinz Herenz Medizinalbedarf GmbH
Rudorffweg 10
21031 Hamburg
Germany

Heinz Herenz Medizinalbedarf GmbH
Osterrade 54
21031 Hamburg
Germany

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