



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 002954 0002 Rev. 01

Manufacturer:

HEYER Medical Co., Ltd.

No.2 Factory, Block B

No.10 Chaobai Street

Yingbin Road West, Yanjiao Development Zone

065201 Sanhe, Langfang City, Hebei Province

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Anesthetic Workstation, Ventilator, Medical Air Compressor, Vaporizer, Respiratory Humidifier.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

BJ19041702

Valid from:

2020-02-25

Valid until:

2023-07-08

Date,

2020-02-25

Christoph Dicks

Head of Certification/Notified Body



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Facility(ies):

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