



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
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 088627 0002 Rev. 01

Manufacturer:

**Ningbo Runyes Medical
Instrument Co., Ltd.**

032 Building, No.456, Tonghui Road
Jiangbei Investment & Pioneering Park C
315033 Ningbo
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

**Product Category(ies): Small Steam Sterilizers,
Diagnostic X-ray Equipment,
Integral Dental Unit Chair**

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.:

SH18869EXT01

Valid from:

2019-04-23

Valid until:

2024-04-22

Date,

2019-04-18

Stefan Preiß



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Facility(ies):

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