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 070744 0016 Rev. 00

Manufacturer:

Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road
Jiangning
211100 Nanjing, Jiangsu
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Nanjing Mindray Bio-Medical Electronics Co., Ltd.
666# Middle Zhengfang Road, Jiangning, 211100 Nanjing, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Rigid Endoscope, Insufflator

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.: SH1955908

Valid from: 2019-08-27
Valid until: 2024-05-26

INTREPRINDEREA MIXTĂ S.R.L. "DUTCHMED-M" IDNO 1009600033367 REPUBLICA MOLDOVA, mun. CHIȘINĂU

Date, 2019-08-27

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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