ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 044751 0176 Rev. 00

Manufacturer:

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: SH1905502

Preceding certificate No.: The certificate is issued for the first time

Valid from: 2019-11-21
Valid until: 2024-11-20

Digitally signed by Furculiță Andrei
Date: 2022.12.28 11:01:13 EET
Reason: MoldSign Signature
Location: Moldova

Date of initial issuance / Rev.00: 2019-11-21

Issue date: 2019-11-21

Christoph Dicks
Head of Certification/Notified Body

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Device(s):	**Risk Classification:**	**CND code:**
Diagnostic Ultrasound System	IIa	Z110401

The validity of this certificate depends on conditions and/or is limited to the following:	./.
Revision History including Changes:	Revision / Issue Date / Report Rev. 00 / 2019-11-21 / SH1905502

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