



Product Service

Certificate

No. Q5 044751 0164 Rev. 06

Holder of Certificate: 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

Certification Mark:



Scope of Certificate: Design and Development, Production, Service and Distribution of: Active Medical Devices(intended) for monitoring, diagnosis, anesthesia, breathing and intensive care; In-vitro Diagnostic Instruments; Non-active accessories for breathing therapy and anesthesia; In-vitro diagnostic reagents and kits(intended) for hematology, clinical chemistry, immunology and cell analysis (For detail information see following pages)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

Report No.: SH2405501

Valid from: 2024-08-15

Valid until: 2026-08-31

Date, 2024-08-15

Christoph Dicks
Head of Certification/Notified Body

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan,
Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Product: Ultrasonic Surgical Instrument

Model: FC-14, FC-23, FC-36, FC-45, FCH-14, FCH-23, FCH-36, FCH-45, FOK-14, FOK-23, FOK-36, FOK-45, FOM-14, FOM-23, FOM-36, FOM-45, PC-14, PC-23, PC-36, PC-45, PCH-14, PCH-23, PCH-36, PCH-45, POK-14, POK-23, POK-36, POK-45, POM-14, POM-23, POM-36, POM-45, POS-14, POS-23, POS-36, POS-45, PCT-14, PCT-23, PCT-36, PCT-45, FOS-14, FOS-23, FOS-36, FOS-45, FCT-14, FCT-23, FCT-36, FCT-45, FO-14, FO-23, FO-36, FO-45

Basic UDI-DI: 69449040AB051100035Y

Classification: IIb (According to Rule 9 of MDR Annex VIII)

Conformity

Assessment Route: Annex IX chapter I&II&III

EMDN code: K020201

Intended Purpose: The Ultrasonic Surgical Instruments are indicated for soft tissue incisions and sealing vessels in open and endoscopic surgery.

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: SGS Belgium NV

Notified Body No. : 1639

Identification of the Certificate: CN23/00003444

Start of CE-Marking: 2024-5-16

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan,
Shenzhen, 518057, P. R. China

Manufacturer SRN: CN-MF-000014156

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Product: Ultrasonic Surgical & Electrosurgical Energy Platform

Model: UP700, UP700B, UP700C, UP700D

Basic UDI-DI: 69449040AB051100015U

Classification: IIb (According to Rule 9 of MDR Annex VIII)

Conformity

Assessment Route: Annex IX Chapter I&II&III

EMDN code: K020299

Supplementary

information: Transducer: TD55, TD55T.

Intended Purpose: Ultrasonic Surgical & Electrosurgical Energy Platform supplies energy to the ultrasonic surgical Instrument and electrosurgical instruments

We declare that the above mentioned products meet the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT. All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

References to CS: /

Notified Body: SGS Belgium NV

Notified Body No. : 1639

Identification of the Certificate: CN23/00003444

Start of CE-Marking: 2024-5-16

I hereby am appointed as the authorized person to deal with all the registration and quality management affairs in my capacity as Deputy Director of Technical Regulation Department of Shenzhen Mindray Bio-Medical Electronics Co., Ltd, Effective immediately.



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	Введите текст для поиска...									
I.2. Declarația de conformitate CE	Declarația de conformitate CE.pdf	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
					pom-36						
DM000821829	Instrument chirurgical cu ultrasunet				POM-36		China	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	DUTCHMED-M S.R.L.	Rg04-000135	02-05-2025



REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire	Введите текст для поиска...									
I.3. Certificatul CE	Certificat EN ISO 13485.pdf	Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
I.2. Declarația de conformitate CE	Declarația de conformitate CE.pdf				td55						
DM000821762	Transductor pentru chirurgia cu ultrasunet				TD55T		China	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	DUTCHMED-M S.R.L.	Rg04-000135	02-05-2025
DM000821761	Transductor pentru chirurgia cu ultrasunet				TD55		China	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	DUTCHMED-M S.R.L.	Rg04-000135	02-05-2025