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EU Quality Management System Certificate CN23/00003444

The management system of

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, 518057, P.R. China
SRN Number: CN-MF-000014156

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

For the following products
The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 21 October 2024 until 27 June 2028 and remains valid subject to satisfactory surveillance audits.
Recertification audit due date 27 December 2027

Issue 6. Certified since 27 June 2023

Authorised by
Virginie Siloret
Global Medical Device Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 - www.sgs.com

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EU Quality Management System Certificate CN23/00003444, continued

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

Issue 6

Class IIa device
MDA0306, MDS1009, MDS1005 Fluid Management System for supplying irrigation or suction (Model: HP100G, HP200G, HP200L, HP200D)
(Basic UDI-DI: 69449040AB0651000589)
MDA 0204, MDS1009, MDS 1005
4K 3D Video Endoscope used in endoscopy and endoscopic surgery within the peritoneal and thoracic cavity
(Model: M 31030A, M 31000A, M 31030PA, M 31000PA, G 31030A, G 31000A, G 31030PA, G 31000PA)
(Basic UDI-DI: 69449040AB065100068B)

Class IIb device
MDA0312, MDS1009 - EMDN: K020199
Electrosurgical Platform intended for use with monopolar and bipolar accessories for cutting and coagulating tissue
(Model: EP300, EP300B, EP300C, EP300D)
(B-UDI-DI: 69449040AB051100025W)
MDA0312, MDS1005, MDS1009- EMDN: K020299
Ultrasonic Surgical and Electrosurgical Energy Platform to provide power to drive electrosurgical instruments or ultrasonic surgical instruments for surgical treatment (Model: UP700, UP700B, UP700C, UP700D, UP500, UP500B, UP500C, UP500D, UP510, UP510B, UP510C, UP510D, UP703, UP705, UP710, UP713, UP715, UP Platinum)
(Basic UDI-DI: 69449040AB051100015U)
MDA0312, MDS1005- EMDN: K020201
Sterile single-use ultrasonic surgical instruments for soft tissue incisions and sealing vessels in open and endoscopic surgery
(Model: FC-14, FCH-14, FOK-14, FOM-14, PC-14, PCH-14, POK-14, POM-14, POS-14, PCT-14, FOS-14, FCT-14, FO-14, FC-23, FCH-23, FOK-23, FOM-23, PC-23, PCH-23, POK-23, POM-23, POS-23, PCT-23, FOS-23, FCT-23, FO-23, FC-36, FCH-36, FOK-36, FOM-36, PC-36, PCH-36, POK-36, POM-36, POS-36, PCT-36, FOS-36, FCT-36, FO-36, FC-45, FCH-45, FOK-45, FOM-45, PC-45, PCH-45, POK-45, POM-45, POS-45, PCT-45, FOS-45, FCT-45, FO-45)
(Basic UDI-DI: 69449040AB051100035Y)

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EU Quality Management System Certificate CN23/00003444, continued

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

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Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CN/SZX/252762 - SUR 1.7
Authorized representative name and address (if relevant): Shanghai International Holding Corp. GmbH (Europe) ; Eiffestraße 80, 20537 Hamburg, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: adjust the format of model names for device 4K 3D Video Endoscope.

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EU Quality Management System Certificate CN23/00003444, continued

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I)

Issue 6

Sites

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

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, Shenzhen, 518106, P.R. China

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