Declaration of Conformity

CE 0123

Manufacturer:	Nanjing Mindray Bio-Medical Electronics Co., Ltd. 666# Middle Zhengfang Road, Jiangning 211111 Nanjing, Jiangsu, People's Republic of China.
Manufacturer SRN:	CN-MF-000019806
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany
Product:	Rigid Endoscope
Model:	M 01030A、M 01000A、M 01030PA、M 01000PA、G 01030A、G 01000A、G 01030PA、G 01000PA、M 00530A、G 00530A、M 00500A、G 00500A、M 10530A、G 10530A、M 10500A、G 10500A、M 00530PA、G 00530PA、M 00500PA、G 00500PA、M 10530PA、G 10530PA、M 10500PA、G 10500PA
Basic UDI-DI:	69483505AB06510005CP
Classification:	IIa (According to Rule 7 of MDR Annex VIII)
Conformity Assessment Route:	Annex IX excluding CHAPTER II
CND code:	Z12029009、Z12029017

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:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München, Germany.
Notified Body No. :	0123
Identification of the Certificate:	G10 070744 0019
Start of CE-Marking:	**2023-06-30**

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

Place, Date of Issue:	**Nanjing, 2023-11-20**
Signature:	ZhaiPei
Name of Authorized Signatory:	Mr. ZhaiPei
Position Held in Company:	Manager, Technical Regulation

Digitally signed by Prodan Sveatoslav
Date: 2026.05.21 16:52:39 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Attachment of Declaration of Conformity: Applied Standards List-*V3.0*

Applied Standards List

Product: **Rigid Endoscope**

Model: **M 01030A、M 01000A、M 01030PA、M 01000PA、G 01030A、G 01000A、G 01030PA、G 01000PA、M 00530A、G 00530A、M 00500A、G 00500A、M 10530A、G 10530A、M 10500A、G 10500A、M 00530PA、G 00530PA、M 00500PA、G 00500PA、M 10530PA、G 10530PA、M 10500PA、G 10500PA**

Standards Applied:

ISO 14971:2021	Medical devices – Application of risk management to medical devices
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 15223-1-2021	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
EN 60601-1:2006/A2:2021	Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-2-18:2015	Medical electrical equipment – Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices — Part 23: Tests for irritation
ISO 8600-3:2019	Optics and optical instruments -- Medical endoscopes and endoscopic accessories -- Part 3: Determination of field of view and direction of view of endoscopes with optics
ISO 8600-4:2023	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 4: Determination of maximum width of insertion portion
ISO 8600-5:2020	Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 5: Determination of optical resolution of rigid endoscopes with optics
ISO 8600-1:2015	Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements
EN 60601-1-6:2010/A2:2021	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices
EN ISO 17664-1:2021	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
IEC 60601-1-9-2020	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

Issue Date: November 13th, 2023

Declaration for Manufacturer Name Change

To whom it may concern,

Hangzhou Optcla Medical Instrument Co.,Ltd. became a subsidiary of Shenzhen Mindray Bio-Medical Electronics CO.,LTD. in 2012. In order to better develop the market and fully enhance the influence of the "MINDRAY" brand, approved by Tonglu Market Supervision Administration, the manufacturer's name was changed from **Hangzhou Optcla Medical Instrument Co.,Ltd.** of which the address is at **No.2 Fengxiang Road, Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311508, P.R.China.** to **Hangzhou Mindray Medical Technology Co., Ltd.** of which the address is also at **No.2 Fengxiang Road, Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311508, P.R.China.** on June 1st, 2023.

The name change does not affect the normal business development , including but not limited to sales of products, provision of services, participation in tenders and other business acts.

Yang Debo
General Manager
Hangzhou Mindray Medical Technology Co., Ltd.

DoC-OPTCLA-202011-01(2.0)

CE 0197

EC Declaration of Conformity

Manufacturer: Hangzhou Mindray Medical Technology Co., Ltd.
No.2 Fengxiang Road,Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311508，China.

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

We, the manufacturer, herewith declare that the following indicated products meets the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. We are exclusively responsible for the Declaration of Conformity.

Reusable Electrode Surgical Instruments

Group Name: *Reusable Bipolar Surgical Instruments*

Product Name and Model: *See Annex I*

UMDNS Code: 15-579 GMDN code: 32684

Classification: IIb (According to Annex IX, rule 9 of the Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been certified by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Deutschland
Certificate No.: HD 60149639 0001
Issue date: 2020-07-29 Expiry date: 2024-05-26

The designated product(s) is compliant with the following standards and/or other normative documents for which documented evidence for compliance:

EN ISO 13485:2016/ISO 13485:2016	EN 62366-1:2015
EN ISO 10993-1:2009+AC:2010	EN ISO 10993-5:2009
EN ISO 10993-10:2013	IEC 60601-2-18:2009
EN 60601-1:2006+A1:2013	EN 60601-2-2:2009
EN 60601-1-6:2010+A1:2015	EN ISO 17664:2017

All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices. Any modification of the medical device not authorized by the manufacturer will invalidate this declaration.

Place, Date of Issue: Shenzhen 2020.7.15
Signature: Zhai Pei
Name of Authorized Signatory: Mr. Zhai Pei
Position Held in Company: Manager of Technical Regulation Department

Annex I

The annex declares the products included in the above referenced Declaration of Conformity.

No.	Product Name	Product Model
Reusable Electrode Surgical Instruments		
1	Bipolar Curved Maryland Dissecting Forceps	222-53111
2	Bipolar Straight Dissecting Forceps	222-53121
3	Bipolar Cable	999-016
4	Bipolar Straight Dissecting Forceps	222-5S3011
5	Bipolar Straight Dissecting Forceps	222-5S4011
6	Bipolar Curved Maryland Dissecting Forceps	222-5S3021
7	Bipolar Curved Maryland Dissecting Forceps	222-5S4021
8	Bipolar Cable	999-031
9	Bipolar Straight Dissecting Forceps Insert	222-5Y3011
10	Bipolar Straight Dissecting Forceps Insert	222-5Y4011
11	Bipolar Curved Maryland Dissecting Forceps Insert	222-5Y3021
12	Bipolar Curved Maryland Dissecting Forceps Insert	222-5Y4021
13	Reusable Lap Instrument Handle, W/o Ratchet	222-560
14	Insulated Shaft	222-5Y303
15	Insulated Shaft	222-5Y403

DoC-OPTCLA-202008-01(1.0)

CE 0197

EC Declaration of Conformity

Manufacturer: Hangzhou Mindray Medical Technology Co., Ltd.
No.2 Fengxiang Road, Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311508，China.

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany
(DIMDI No.: DE/0000040627)

We, the manufacturer, herewith declare that the following indicated products meets meet the provisions of the Council Directive 93/42/EEC for Medical Device, as amended by 2007/47/EC. We are exclusively responsible for the Declaration of Conformity.

Reusable Electrode Surgical Instruments

Group Name: *Reusable Monopolar Surgical Instruments*

Product Name and Model: *See Annex I*

UMDNS Code: 15-579 GMDN code: 33596

Classification: IIb (According to Annex IX, rule 9 of the Directive 93/42/EEC)

Compliance of the designated product(s) with the directives has been certified by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Deutschland
Certificate No.: HD 60149639 0001
Issue date: 2020-07-29 Expiry date: 2024-05-26

The designated product(s) is compliant with the following standards and/or other normative documents for which documented evidence for compliance:

EN ISO 13485:2016/ISO 13485:2016	EN 62366-1:2015
EN ISO 10993-1:2009+AC:2010	EN ISO 10993-5:2009
EN ISO 10993-10:2013	EN ISO 10993-7:2008+AC:2009
EN 60601-1:2006+A1:2013	EN 60601-2-2:2009
EN 60601-1-6:2010+A1:2015	EN ISO 11135:2014

All supporting documentations are retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of the manufacturer.

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices. Any modification of the medical device not authorized by the manufacturer will invalidate this declaration.

Place, Date of Issue: Shenzhen 2020.07.25
Signature: Zhai Pei
Name of Authorized Signatory: Mr. Zhai Pei
Position Held in Company: Manager of Technical Regulation Department

Annex I

The annex declares the products included in the above referenced Declaration of Conformity.

No.	Product Name	Product Model
Reusable Electrode Surgical Instruments		
1	Hook Tip Coagulation Electrode	222-51110
2	Ball Tip Coagulation Electrode	222-51220
3	Spatula Tip Coagulation Electrode	222-51440
4	Rod Tip Coagulation Electrode	222-51610
5	KELLY Dissecting and Grasping forceps, Maryland	222-5S3013
6	KELLY Dissecting and Grasping forceps, Maryland	222-5T3013
7	KELLY Dissecting and Grasping forceps, long, Maryland	222-5S3023
8	KELLY Dissecting and Grasping forceps, long, Maryland	222-5T3023
9	Straight Dissecting and Grasping forceps. atraumatic	222-5S3043
10	Straight Dissecting and Grasping forceps. atraumatic	222-5T3043
11	Dissecting and Grasping forceps. atraumatic	222-0S3103
12	Dissecting and Grasping forceps. atraumatic	222-0T3103
13	Dissecting and Grasping forceps. right-angled	222-5S3123
14	Dissecting and Grasping forceps. right-angled	222-5T3123
15	Dissecting and Grasping forceps. right-angled	222-0S3133
16	Dissecting and Grasping forceps. right-angled	222-0T3133
17	Bowel Grasper, fenestrated, short	222-5S3213
18	Bowel Grasper, fenestrated, short	222-5T3213
19	Grasping forceps, atraumatic, spoon-shaped	222-5S3223
20	Grasping forceps, atraumatic, spoon-shaped	222-5T3223
21	MANHES Dissecting and Grasping forceps, "duckbill"	222-5S3283
22	MANHES Dissecting and Grasping forceps, "duckbill"	222-5T3283
23	Bowel Grasper, fenestrated	222-5S3303

24	Bowel Grasper, fenestrated	222-5T3303
25	Grasping forceps, atraumatic	222-5S3333
26	Grasping forceps, atraumatic	222-5T3333
27	MANHES Grasping forceps， "tiger-jaws", 2X4 teeth	222-5S3363
28	MANHES Grasping forceps， "tiger-jaws", 2X4 teeth	222-5T3363
29	Grasping forceps,2X4 teeth	222-5S3393
30	Grasping forceps,2X4 teeth	222-5T3393
31	Claw forceps，2X3 teeth，short	222-0S3403
32	Claw forceps，2X3 teeth，short	222-0T3403
33	Claw forceps，2X3 teeth	222-0S3413
34	Claw forceps，2X3 teeth	222-0T3413
35	SAWALHE Tissue Grasping forceps	222-0S3423
36	SAWALHE Tissue Grasping forceps	222-0T3423
37	CROCE-OLMI Grasping forceps, atraumatic, curved	222-5S3453
38	CROCE-OLMI Grasping forceps, atraumatic, curved	222-5T3453
39	VANCAILLIE Adhesion Forceps, one jaw fenestrated	222-5S3493
40	VANCAILLIE Adhesion Forceps, one jaw fenestrated	222-5T3493
41	BABCOCK Grasping forceps	222-5S3553
42	BABCOCK Grasping forceps	222-5T3553
43	BABCOCK Grasping forceps	222-0S3573
44	BABCOCK Grasping forceps	222-0T3573
45	VANCAILLIE Oviduct Forceps	222-5S3583
46	VANCAILLIE Oviduct Forceps	222-5T3583
47	Atraumatic Grasping forceps	222-5S3633
48	Atraumatic Grasping forceps	222-5T3633
49	Dissecting and Grasping forceps, "alligator jaws"	222-5S3773
50	Dissecting and Grasping forceps, "alligator jaws"	222-5T3773
51	DeBAKEY Grasping forceps, curved and slender jaws	222-5S3813

52	DeBAKEY Grasping forceps, curved and slender jaws	222-5T3813
53	Spoon forceps	222-0S4883
54	Spoon forceps	222-0T4883
55	MANHES biopsy forceps	222-5S3903
56	MANHES biopsy forceps	222-5T3903
57	Scissors,spoon-shaped blades, serrated, curved	222-5S3012
58	Scissors,spoon-shaped blades, serrated, curved	222-5S4012
59	METZENBAUM Scissors, curved	222-5S3022
60	METZENBAUM Scissors, curved	222-5S4022
61	Scissors, straight	222-5S3092
62	Scissors, straight	222-5S4092
63	Grasping forceps, w specially fine atraumatic serration	222-5S3473
64	Grasping forceps, w specially fine atraumatic serration	222-5T3473
65	Grasping forceps, w specially fine atraumatic serration	222-5S4473
66	Grasping forceps, w specially fine atraumatic serration	222-5T4473
67	KELLY Dissecting and Grasping forceps, Maryland	222-5S4013
68	Atraumatic Grasping forceps	222-5T4633
69	CROCE-OLMI Grasping forceps, atraumatic, curved	222-5T4453
70	KELLY Dissecting and Grasping forceps, Maryland	222-5T4013
71	KELLY Dissecting and Grasping forceps, long, Maryland	222-5T4023
72	Dissecting and Grasping forceps. right-angled	222-5T4123
73	Monopolar cable	999-030
74	Reusable Lap Instrument Handle, W/o Ratchet	222-550
75	Reusable Lap Instrument Handle, With Ratchet	222-551
76	Reusable Lap Instrument Handle, W/o Ratchet	222-560
77	Insulated Shaft	222-5Y301
78	Insulated Shaft	222-0Y301
79	Insulated Shaft	222-5Y401

80	Insulated Shaft	222-5Y303
81	Insulated Shaft	222-5Y403
82	Claw forceps Insert，2X3 teeth	222-0Y3413
83	SAWALHE Tissue Grasping forceps Insert	222-0Y3423
84	MANHES Grasping forceps Insert，"tiger-jaws", 2X4 teeth	222-5Y3363
85	Atraumatic Grasping forceps Insert	222-5Y3633
86	Scissors Insert, spoon-shaped blades, serrated, curved	222-5Y3012
87	KELLY Dissecting and Grasping forceps Insert, Maryland	222-5Y3013
88	KELLY Dissecting and Grasping forceps Insert, long, Maryland	222-5Y3023
89	Straight Dissecting and Grasping forceps Insert. atraumatic	222-5Y3043
90	Dissecting and Grasping forceps Insert. atraumatic	222-0Y3103
91	Dissecting and Grasping forceps Insert. right-angled	222-5Y3123
92	Dissecting and Grasping forceps Insert. right-angled	222-0Y3133
93	Bowel Grasper Insert, fenestrated, short	222-5Y3213
94	Grasping forceps Insert, atraumatic, spoon-shaped	222-5Y3223
95	MANHES Dissecting and Grasping forceps Insert, "duckbill"	222-5Y3283
96	Bowel Grasper Insert, fenestrated	222-5Y3303
97	Grasping forceps Insert, atraumatic	222-5Y3333
98	Grasping forceps Insert,2X4 teeth	222-5Y3393
99	Claw forceps Insert，2X3 teeth，short	222-0Y3403
100	CROCE-OLMI Grasping forceps Insert, atraumatic, curved	222-5Y3453
101	VANCAILLIE Adhesion Forceps Insert, one jaw fenestrated	222-5Y3493
102	BABCOCK Grasping forceps Insert	222-5Y3553
103	BABCOCK Grasping forceps Insert	222-0Y3573
104	VANCAILLIE Oviduct Forceps Insert	222-5Y3583
105	Dissecting and Grasping forceps Insert, "alligator jaws"	222-5Y3773
106	DeBAKEY Grasping forceps Insert, curved and slender jaws	222-5Y3813
107	Spoon forceps Insert	222-0Y4883

108	MANHES biopsy forceps Insert	222-5Y3903
109	METZENBAUM Scissors Insert, curved	222-5Y3022
110	METZENBAUM Scissors Insert, curved	222-5Y4022
111	Scissors Insert, straight	222-5Y3092
112	Scissors Insert, straight	222-5Y4092
113	Grasping forceps Insert, w specially fine atraumatic serration	222-5Y3473
114	Grasping forceps Insert, w specially fine atraumatic serration	222-5Y4473
115	KELLY Dissecting and Grasping forceps Insert, Maryland	222-5Y4013
116	KELLY Dissecting and Grasping forceps Insert, long, Maryland	222-5Y4023
117	Dissecting and Grasping forceps Insert. right-angled	222-5Y4123
118	Atraumatic Grasping forceps Insert	222-5Y4633
119	Scissors Insert, spoon-shaped blades, serrated, curved	222-5Y4012
120	CROCE-OLMI Grasping forceps Insert, atraumatic, curved	222-5Y4543
121	CROCE-OLMI Grasping forceps Insert, atraumatic, curved	222-5Y4453

Declaration of Conformity V1.0

Declaration of Conformity

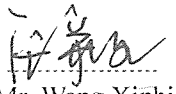
CE

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:	/
EC-Representative	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Light Cable
Model:	LC0005S, LC0003S
Basic UDI-DI:	69449040LC0005S********6Y
Classification:	I (According to Rule 13 of MDR Annex VIII)
Conformity Assessment Route:	Article 52.7
GMDN code:	35158

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:	/
Start of CE-Marking:	

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

Place, Date of Issue:	Shenzhen,2021.6.4
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Attachment of Declaration of Conformity: Applied Standards List-V1.0

Applied Standards List

Product: Light Cable

Model: LC0005S, LC0003S

Standards Applied:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – Part1: General requirements
EN60601-1:2006/ A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6: 2010/A1:2015	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 62366-1:2015	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664:2017	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
EN 60601-2-18	Medical electrical equipment-Part 2-18:Particular requirements for the basic safety and essential performance of endoscopic equipment
EN 62471	Photobiological safety of lamps and lamp systems.
EN 60825-1	Safety of laser products – Part 1: Equipment classification and requirements.

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

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

TÜV SÜD 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. 04

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

SRN Manufacturer - CN-MF-000014156

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. 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:G10 044751 0176 Rev. 04

Report No.: SH2405511

Preceding Certificate No.: G10 044751 0176 Rev. 03

Valid from: 2024-11-21
Valid until: 2029-11-20

Date of Initial Issuance: 2019-11-21

Issue date: 2024-10-08

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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

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. 04

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The patient monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters.

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The Vital Signs Monitor is intended for monitoring, displaying, reviewing, storing, alarming, and transferring of multiple physiological parameters.

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The Central Monitoring System is intended for monitoring vital sign information.

Classification:	Class IIb
Device Group:	Z120306 - VITAL SIGNS TELEMETRY INSTRUMENTS (ECG, NIPB, EtCO2, SpO2, RESPIRATION,...)
Intended Purpose:	The Telemetry Monitor is intended for monitoring, displaying, reviewing, storing, alarming and transferring of multiple physiological parameters

Classification:	Class IIa
Device Group:	Z120503 - ELECTROCARDIOGRAPHS
Intended Purpose:	/

Classification:	Class IIb
Device Group:	C020401 - EXTERNAL CARDIOVERSION DEFIBRILLATOR ELECTRODE PADS
Intended Purpose:	The external defibrillation paddles are intended for connecting with the patient and the defibrillator/monitor to perform defibrillation therapy and ECG detecting.

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The pulse oximeter is intended for continuously monitoring, spot checking, displaying, storing and transferring oxygen saturation and pulse rate of single patient.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ

Benannt durch/Designated by
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www.zlg.de
BS-MDR-099

TÜV SÜD
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. 04

Classification:	Class IIb
Device Group:	V030102 - BODY TEMPERATURE MONITORING PROBES
Intended Purpose:	The temperature probe is intended for continuous patient temperature measurement and control applications.

Classification:	Class IIb
Device Group:	Z120302 - VITAL SIGNS MONITORING INSTRUMENTS
Intended Purpose:	The SpO2 Sensor is intended for connecting with Mindray medical devices that support SpO2 measurements for measuring the arterial oxygen saturation and pulse rate of patients.

Classification:	Class IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	The ventilator is intended for providing ventilation assistance and breathing support for patients.

Classification:	Class IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	The air compressor is intended for delivering dry and clean high pressure air to the ventilator or anesthesia machine and provide breathing support for patient.

Classification:	Class IIa
Device Group:	Z110401 - ULTRASOUND SCANNERS Z110402 - ULTRASOUND PROBES
Intended Purpose:	/

Classification:	Class IIb
Device Group:	Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS
Intended Purpose:	The Radiography System is intended for performing radiographic X-ray examinations on all pediatric and adult patients.

Classification:	Class IIa
Device Group:	Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose:	/

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

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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. 04

Classification:	Class IIa
Device Group:	R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	V030101 - THERMOMETERS
Intended Purpose:	/
Classification:	Class IIa
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	/
Classification:	Class IIb
Device Group:	Z120301 - ANAESTHESIA AND PULMONARY VENTILATION SUPPORT INSTRUMENTS
Intended Purpose:	The Anesthesia System is a device used to deliver fresh gas, to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation through mechanical or manual ventilation.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2019-11-21	SH1905502	-
01	2021-10-28	SH2005505	-
02	2024-02-22	SH2205506	Supplemented: Device(s)/group of device(s) added
03	2024-07-05	SH2105504/SH2305506	Restricted: Product(s) reclassified Supplemented: Device(s)/group of device(s) added
04	2024-11-21	SH2405511	Renewal of certificate Supplemented: Device(s)/group of device(s) added

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D-ZM-11321-01-00

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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:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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

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No. Q5 044751 0164 Rev. 06

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

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

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)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

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)

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For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor , Defibrillator/Monitor and Accessories, Electrocardiograph, Anesthesia Machine and accessories, Ventilator, Air compressor, Endoscope Camera System, Endoscope Light Source and accessories, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for invitro diagnostic use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer, Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Coagulation Analyzer and Accessories, Coagulation Reagents, Calibrators and Controls for Coagulation Analyzer, Automated Digital Cell Morphology Analyzer , Ion-Selective Electrodes, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag, Tympanic Thermometer, Microbial Analysis System, Reagents for Urine Analyzer, Generator, Nasal Mask/Nasal Prong, Detector and Imaging System.

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认 证 证 书

证书号. Q5 044751 0164 Rev. 06

证书持有者： **深圳迈瑞生物医疗电子股份有限公司**

中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

认证标志：

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

认证范围： **设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息范围见附件)**

认证机构TÜV SÜD产品服务有限公司证明上述公司已经建立并运行了满足所列标准要求的质量管理体系。
TÜV 南德集团检测、认证、审定与核查准则所有适用要求也须得到遵守。详情及证书有效期请见
www.tuvsud.com/ps-cert?q=cert:Q5 044751 0164 Rev. 06

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发证日期， 2024-08-15

C. Dicks

Christoph Dicks

Head of Certification/Notified Body

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证书号. Q5 044751 0164 Rev. 06

认证标准：

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
医疗器械 - 质量管理体系 - 用于法规的要求

生产场地：

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市南山区高新技术产业园科技南十二路迈瑞大厦
518057

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

深圳迈瑞生物医疗电子股份有限公司
中华人民共和国深圳市光明区南环大道1203号, 518106

设计和开发、生产、服务和分销：有源医疗器械用于监护、诊断、麻醉、呼吸和重症监护；体外诊断设备；无源附件用于呼吸治疗和麻醉；体外诊断试剂和试剂盒用于血球、临床生化、免疫及细胞分析。(具体信息见附件)

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覆盖产品范围为:

医用电子设备（包括病人监护仪和附件、生命体征监测仪、中心监护系统、数字遥测监护系统、血氧饱和度监护仪、体温探头、流量传感器、动态血压监测仪、除颤监护仪和附件、心电图机、麻醉机和附件、呼吸机、空压机、内窥镜摄像系统、冷光源及附件、超声诊断设备和附件、数字化医用X射线摄影系统、医用X射线摄影系统、血液细胞分析仪、生化分析仪、尿液分析仪、酶标仪、体外诊断用洗板机、全自动化学发光免疫分析仪、流式细胞仪、（全自动）样本处理系统、 全自动推片染色机、糖化血红蛋白分析仪、特定蛋白免疫分析仪），以及血液细胞分析仪用试剂、生化分析仪用试剂、化学发光免疫试剂、化学发光免疫校准品和质控品、流式细胞仪用试剂、糖化血红蛋白分析仪用试剂、糖化血红蛋白分析仪用校准品和质控品、凝血仪器及附件、凝血试剂、凝血校准质控品、全自动细胞形态学分析仪、离子选择性电极、一次性麻醉面罩、可复用的麻醉面罩、呼吸面罩、一次性呼吸回路、可复用的呼吸回路、热湿交换器、过滤器、呼吸囊、红外耳温计、微生物分析用仪器、尿液分析仪用试剂、压力发生器、鼻罩/鼻塞、探测器及成像系统

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