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深圳迈瑞生物医疗电子股份有限公
深圳国立商事认证中心

证明书

CERTIFICATE



中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书 CERTIFICATE



号码 No. 204403A0/026326

兹证明：在所附符合性声明上的深圳迈瑞生物医疗电子股份有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. on the annexed DECLARATION OF CONFORMITY is genuine.

China Council for the Promotion
of International Trade

授权签字：用章

Authorized
Signature: Xu Dajun

日期：2020年05月15日
(Date: May. 15, 2020)



认字第20011089号

兹证明前面文书上中国国际
贸易促进委员会商事证明专用章
CCPIT(24)的印章和授权签
字人徐大军的签字属实。



中华人民共和国外交部(440)
二〇二〇年五月十九日 广州

徐大军



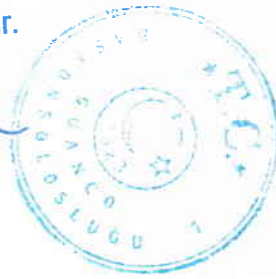
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T.C.
GUANCO BAŞKONSOLOSLUĞU
İşbu belge üzerindeki imza ve mührün
Guangdong Dışişleri Ofisi'ne
ait bulunduğu, metne şamii olmamak
üzere onaylanır.

Selçuk Alkan

Selçuk ALKAN
Muavin Konsolos
Vice Consul



No: 22/05/2020/605

Tarife: 5/III/3a

Harç: 133 Yuan

Makbuz No: 26955686



Declaration of Conformity



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

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

Product Name: Diagnostic Ultrasound System (including accessories)
Digital Ultrasonic Diagnostic Imaging System
(including accessories)

Model: **Attachment I**

Accessories list: **Attachment II**

Classification: IIa (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

Product Name: Patient Monitor (including accessories)
Pulse Oximeter (including accessories)
Telemetry Monitoring System (including accessories)
Telemetry Monitor (including accessories)
Vital Signs Monitor (including accessories)

Model: **Attachment I**

Accessories list: **Attachment II**

Classification: IIb (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

Product Name: Anesthesia Machine (including accessories)
Anesthesia System (including accessories)

Model: **Attachment I**

Accessories list: **Attachment II**

Classification: IIb (According to Rule 11 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

Product Name: Defibrillator/Monitor (including accessories)

Ventilator (including accessories)

Automated External Defibrillator (including accessories)

Model: Attachment I

Accessories list: Attachment II

Classification: IIb (According to Rule 9 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

Product Name: Electrocardiograph (including accessories)

Model: Attachment I

Accessories list: Attachment II

Classification: IIa (According to Rule 10 of MDD Annex IX)

Conformity Assessment Route: MDD Annex II excluding(4)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC concerning Medical Device, as amended by 2007/47/EC. All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München, Germany.

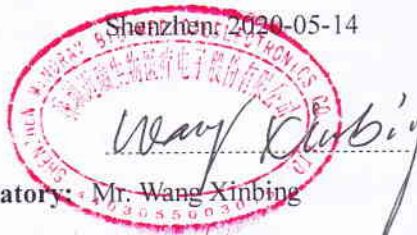
Notified Body No. : 0123

Place, Date of Issue: Shenzhen, 2020-05-14

Signature:

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation



Patient Monitor, Pulse Oximeter, Telemetry Monitoring System, Telemetry Monitor and Vital Signs

Monitor List

No.	Product Name	Model/Configuration
1	Central Monitoring System	BeneVision
2	Patient Monitor	uMEC12
3	Patient Monitor	iMEC12
4	Patient Monitor	iPM 10
5	Patient Monitor	iPM 12
6	Pulse Oximeter	PM-60
7	Patient Monitor	iMEC10
8	Patient Monitor	iPM 8
9	Telemetry Monitoring System	TMS-6016
10	Vital Signs Monitor	VS-600
11	Patient Monitor	iMEC8
12	Patient Monitor	iMEC5
13	Patient Monitor	iMEC6
14	Patient Monitor	iMEC7
15	Patient Monitor	iMEC15
16	Patient Monitor	iPM 5
17	Patient Monitor	iPM 6
18	Patient Monitor	iPM 7
19	Patient Monitor	iMEC15S
20	Vital Signs Monitor	VS-900
21	Patient Monitor	BeneVision N19
22	Patient Monitor	BeneVision N22
23	Patient Monitor	uMEC10
24	Patient Monitor	uMEC15
25	Patient Monitor	BeneVision N12

26	Patient Monitor	BeneVision N12C
27	Patient Monitor	BeneVision N15
28	Patient Monitor	BeneVision N17
29	Telemetry Monitor	TM80
30	Patient Monitor	BeneVision N1
31	Patient Monitor	ePM 10
32	Patient Monitor	ePM 12
33	Patient Monitor	ePM 15
34	Patient Monitor	ePM 10M
35	Patient Monitor	ePM 12M
36	Patient Monitor	ePM 15M
37	Patient Monitor	ePM 12A
38	Patient Monitor	ePM 15A
39	Patient Monitor	ePM 12MA
40	Patient Monitor	uMEC6
41	Patient Monitor	uMEC7
42	Patient Monitor	uMEC15S
43	Vital Signs Monitor	VS-800
44	Patient Monitor	BeneView T8

Anesthesia Machine and Anesthesia System List

No.	Product Name	Model/Configuration
1	Anesthesia Machine	WATO EX-55
2	Anesthesia Machine	WATO EX-65
3	Anesthesia Machine	WATO EX-20
4	Anesthesia Machine	WATO EX-30
5	Anesthesia Machine	WATO EX-35
6	Anesthesia System	A7
7	Anesthesia Machine	WATO EX-65 Pro

Electrocardiograph list

No.	Product Name	Model
1	Electrocardiograph	BeneHeart R3
2	Electrocardiograph	BeneHeart R12
3	Electrocardiograph	Beneheart R3A
4	Electrocardiograph	Beneheart 12A

Attachment II

Accessories List

1. The accessories of Diagnostic Ultrasound System and Digital Ultrasonic Diagnostic Imaging System

No.	Product Description	Model	P/N
1	Ultrasonic Transducer	SC6-1U	120-004524-00
2	Ultrasonic Transducer	C4-1U	120-004640-00
3	Ultrasonic Transducer	C6-2GU	120-004609-00
4	Ultrasonic Transducer	C11-3U	120-004603-00
5	Ultrasonic Transducer	L14-5WU	120-004219-00
6	Ultrasonic Transducer	L16-4HU	120-004654-00
7	Ultrasonic Transducer	P10-4U	120-004615-00
8	Ultrasonic Transducer	P7-3U	120-004634-00
9	Ultrasonic Transducer	P7-3TU	120-004646-00
10	Ultrasonic Transducer	SC6-1E	120-004398-00
11	Ultrasonic Transducer	SD8-1E	120-005172-00
12	Ultrasonic Transducer	L20-5E	120-005183-00
13	Ultrasonic Transducer	6LB7E	120-005178-00
14	Ultrasonic Transducer	6C2P	120-001503-00
15	Ultrasonic Transducer	P7-3P	120-004588-00
16	Ultrasonic Transducer	C11-3s	120-002715-00