Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 044751 0167 Rev. 02

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

Product Category(ies):

Patient Monitoring Devices,
Vital Signs Monitor,
Center Monitoring System,
Telemetry Monitoring System,
Ambulatory Blood Pressure Monitor,
Pulse Oximeter, Temperature Probe,
SPO2 Sensors, Electrocardiograph,
Ventilator, Anesthetic Vaporizer,
Air compressor,
Ultrasonic Diagnostic Equipment,
Ultrasonic Transducer,
Digital Radiography System,
Radiography System

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1905503

Digitally signed by Poiata Vitalie
Date: 2023.01.06 16:08:57 EET
Reason: MoldSign Signature
Location: Moldova

Valid from: 2019-11-13
Valid until: 2024-05-26

Date, 2019-11-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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

Benannt durch/Designated by
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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 044751 0167 Rev. 02

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

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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

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
tuv-sud.com/ps-cert

Scope of Certificate:

**Design and development,
production 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). See also notes overleaf.

Report No.: SH2005501

Valid from: 2020-09-01
Valid until: 2023-08-31

Date, 2020-07-24

Christoph Dicks
Head of Certification/Notified Body

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 044751 0164 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

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

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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 044751 0164 Rev. 02

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,
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,
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit,
Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 15, 2016

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Zhai Pei
Engineer of Technical Regulation Department
Mindray Building, Keji 12th Road South,
Hi-tech Industrial Park, Nanshan
Shenzhen, Guangdong 518057
CHINA

Re: K162845
Trade/Device Name: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 28, 2016
Received: October 11, 2016

Dear Zhai Pei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162845

Device Name

DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Indications for Use *(Describe)*

The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic,adult cephalic,trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric and peripheral vessel exams.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: N/A

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2,3, 4,6,7
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,3, 4,6,7
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Small Organ	N	N	N		N	N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6,7
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 3C5A

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Small Organ								
	Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 7L4A

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
	Small Organ	N	N	N		N	N	N	Note 1,2, 4,6,7,8
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: L7-3

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
	Small Organ	N	N	N		N	N	N	Note 1,2, 4,6,7
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,6,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,6,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Transducer: D7-2E
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Dopple	Amplitude Doppler	Combined	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6
	Abdominal	N	N	N		N	N	N	Note 1, 3, 4, 6
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Transducer: L14-6NE
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Dopple	Amplitude Doppler	Combined	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1,2, 4,7
	Small Organ	N	N	N		N	N	N	Note 1,2, 4,7,8
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2, 4,7
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2, 4,7
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2, 4,7
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Transducer: V11-3
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Dopple	Amplitude Doppler	Combined	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Abdominal								
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-vaginal	N	N	N		N	N	N	Note 1, 2, 4,6,7
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Transducer: P4-2
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (Track 1	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Dopple	Amplitude Doppler	Combined	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	N	Note 1, 2,4,6,7
	Intra-operative								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6,7
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B,Power + PW +B.

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes.

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Smart3D

Note 3:4D(Real-time 3D)

Note 4: iScape

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K162845.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5604
Fax: +86 755 2658 2680

Contact Person:
Zhai Pei
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 28, 2016

2. Device Name: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

3. Device Description:

DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-mode, M-mode, PW-mode, CW mode, Color-mode, Power/Dirpower mode, THI mode, 3D/4D mode, iScape mode, TDI mode,

Color M mode, Biopsy Guidance, Elastography, or the combined mode (i.e. B/M-Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 3 MHz to 10.0MHz.

4. Intended Use:

The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric and peripheral vessel exams.

5. Comparison with Predicate Devices:

DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1	Mindray	DC-N3	K140030
2	Mindray	DC-60	K152545
3	Mindray	Resona 7	K162267

The modified DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations. The subject device also has the same intended uses and basic operating modes as the predicate devices.

■ Subject device DC-40/DC-35/DC-45/DC-40S/DC-40 Pro has the same intended uses as the predicated device DC-N3 (K140030).

Items	**Subject Device** DC-40/DC-35/DC-45/DC-40S/DC-40 Pro	**Predicate device** DC-N3 (K140030)
Intended Use	DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates.	The DC-N3 diagnostic ultrasound system is applicable for adults, pregnant women, pediatric patients and neonates.

	It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric and peripheral vessel exams.	It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional), musculo-skeletal(superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

- The patient contact materials of the transducers are tested under ISO 10993-1.
- The acoustic power levels of the DC-40/DC-35/DC-45/DC-40S/DC-40 Pro are below the limits of FDA, which are the same as the predicated device DC-N3 (K140030).
- DC-40/DC-35/DC-45/DC-40S/DC-40 Pro is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-N3 (K140030).
- The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro has the same imaging modes as the predicated devices.
- All of the functions of DC-40/DC-35/DC-45/DC-40S/DC-40 Pro are the same as the predicated devices.
- The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro has same tranducers with the predicated devices.

6. Non-clinical Tests:

DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- AAMI/ANSI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- AAMI/ANSI/IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304: Medical device software - Software life cycle processes
- IEC:62366:Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- ISO14971: Medical devices - Application of risk management to medical devices
- UD 2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- UD 3 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

7. Clinical Studies

Not applicable. The subject of this submission, DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

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SCC Accredited CB-MS OCSM Accrédité CCN

America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder:

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 ISO 9001

Scope of Certificate: **See Page 2 for Overall Scope Statement.**

Standard(s): **ISO 9001:2015**

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: **SH2005501**

Effective Date: **2020-08-12**

Expiry Date: **2023-06-30**

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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SCC Accredited CB-MS OCSM Accrédite CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services

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SCC Accredited CB-MS OCSM Accrédite CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

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SCC Accredited CB-MS OCSM Accrédite CCN

TÜV SÜD America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies)

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

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including 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, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Date of Issue: 2020-08-20

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Manager, US Certification Body,
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Declaration of Conformity

CE 0123

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

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

Product: Diagnostic Ultrasound System

Model: DC-40, DC-41, DC-42, DC-43, DC-44, DC-45, DC-40S, DC-40 Pro, DC-40 Exp, DC-40T

Supplementary information: Included are following transducers: 3C5A, 6C2, L14-6, L12-3E, 7L4A, V10-4B, 7L5, L7-3, L14-6NE, CB10-4E, P7-3, D7-2E, V11-3, P4-2, CW5s and following needle-guided brackets: NGB-004, NGB-005, NGB-006, NGB-007, NGB-011, NGB-016.

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.

Standards Applied:
List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

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

Notified Body No. : 0123

Start of CE-Marking: 2016.3.8

Place, Date of Issue: Shenzhen 2016.3.8

Signature: .....

Name of Authorized Signatory: Mr. Tan Chuanbin

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: **Diagnostic Ultrasound System**

Model: DC-40, DC-41, DC-42, DC-43, DC-44, DC-45, DC-40S, DC-40 Pro, DC-40 Exp, DC-40T

Standards Applied:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO15223-1:2012	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied-Part 1: General Requirements
EN60601-1:2006/AC:2010	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN60601-1-2:2007/AC:2010	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	Medical electrical equipment - Part 1-6: General Requirements for basic safety and essential performance -Collateral standard: usability
EN 60601-2-37:2008	Medical electrical equipment -- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 62304:2006/AC:2008	Medical device software - Software life-cycle processes
EN 62366:2008	Medical devices -- Application of usability engineering to medical devices
EN ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：粤食药监械出 20211431 号
Certificate NO.：粤食药监械出 20211431 号

产品名称：见附页
Product(s)：See Attachment

规格型号：见附页
Model：**See Attachment**

产品注册或备案凭证号：见附页
Registration certificate(s)：See Attachment

生产企业：深圳迈瑞生物医疗电子股份有限公司
Manufacturer：**SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO.,LTD**

生产企业住所：深圳市南山区高新技术产业园区科技南十二路迈瑞大厦 1-4 层
Address of manufacturer: 1-4/F, Mindray Building, keji 12th Road South, High-Tech Industrial Park, Nanshan, Shenzhen, P. R. China

生产许可或备案凭证号：粤食药监械生产许 20010352 号
Manufacturing License(s)：粤食药监械生产许 20010352 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2023 年 12 月 29 日
This certification valid until:29/12/2023

备注：/
Remark：/

2021 年 12 月 30 日
（出具单位盖章）

广东省药品监督管理局
出口销售证明专用章

医疗器械产品出口销售证明书附页

ATTACHMENT OF CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号 Certificate No.：粤食药监械出 20211431 号

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
1	反三碘甲状腺原氨酸校准品 rT3 Calibrators	C0：1×1.0 mL，C1：1×1.0 mL，C2：1×1.0 mL。 C0：1×1.0 mL，C1：1×1.0 mL，C2：1×1.0 mL。	粤械注准 20172401540
2	腺苷脱氨酶（ADA）测定试剂盒（酶比色法） Adenosine Deaminase Kit (Enzymatic Colorimetric Method)	30 mL R1：1×20 mL，R2：1×10 mL； 54 mL R1：1×36 mL，R2：1×18 mL； 60 mL R1：1×40 mL，R2：1×20 mL； 90 mL R1：1×60 mL，R2：1×30 mL； 100 mL R1：2×32 mL，R2：2×18 mL； 108 mL R1：2×36 mL，R2：2×18 mL； 300 mL R1：1×200 mL，R2：1×100 mL； 校准品（选配）：1×1.0 mL。 30 mL R1：1×20 mL，R2：1×10 mL； 54 mL R1：1×36 mL，R2：1×18 mL； 60 mL R1：1×40 mL，R2：1×20 mL； 90 mL R1：1×60 mL，R2：1×30 mL； 100 mL R1：2×32 mL，R2：2×18 mL； 108 mL R1：2×36 mL，R2：2×18 mL； 300 mL R1：1×200 mL，R2：1×100 mL； calibrator：1×1.0 mL。	粤械注准 20152400322
3	直接胆红素（D—bil）测定试剂盒（重氮盐法） Bilirubin Direct Kit (DSA Method)	35 mL R1：1×25 mL，R2：1×10 mL；90 mL R1：4×18 mL，R2：1×18 mL；100 mL R1：4×20 mL，R2：1×20 mL；160 mL R1：4×32 mL，R2：4 × 8 mL；180 mL R1：3×48 mL，R2：3×12 mL；240 mL R1：4×48 mL，R2：4×12 mL；625 mL R1：2×250 mL，R2：1×125 mL	粤械注准 20152400330

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		35 mL R1：1×25 mL，R2：1×10 mL；90 mL R1：4×18 mL，R2：1×18 mL；100 mL R1：4×20 mL，R2：1×20 mL；160 mL R1：4×32 mL，R2：4×8 mL；180 mL R1：3×48 mL，R2：3×12 mL；240 mL R1：4×48 mL，R2：4×12 mL；625 mL R1：2×250 mL，R2：1×125 mL	
4	CD3/CD16+56/CD45/CD19 检测试剂(流式细胞法-FITC/PE/PerCP/APC) CD3-FITC/CD16+56-PE/CD45-PerCP/CD19-APC Reagent	50 人份/盒 50 tests	国械注准 20193401556
5	丙型肝炎病毒抗体质控品 Anti-HCV Control	阴性质控品：3×2.0 mL，阳性质控品：3×2.0 mL；阴性质控品：6×2.0 mL，阳性质控品：6×2.0 mL P：3×2.0 mL，N：3×2.0 mL；P：6×2.0 mL，N：6×2.0 mL	国械注准 20163400205
6	胰岛素（Insulin）测定试剂盒（化学发光免疫分析法） Insulin(CLIA)	2×30 人份/盒、2×50 人份/盒、2×100 人份/盒 2×30tests、2×50tests、2×100tests	粤械注准 20152400847
7	全数字便携式超声诊断系统 Digital Ultrasonic Diagnostic Imaging System	DP-30、DP-30T DP-30、DP-30T	粤械注准 20142060192
8	γ—谷氨酰转移酶（γ—GT）测定试剂盒（IFCC 法） Gamma-Glutamyltransferase Kit (Szasz Method/IFCC stand)	35mL：R1：1×25 mL，R2：1×10 mL；176 mL：R1：4×35 mL，R2：2×18 mL；200 mL：R1：4×40 mL，R2：2×20 mL；300 mL：R1：4×60 mL，R2：2×30 mL；304 mL：R1：6×40 mL，R2：2×32 mL；438 mL：R1：6×57 mL，R2：3×32 mL；625 mL：R1：2×250 mL，R2：1×125 mL。 35mL：R1：1×25 mL，R2：1×10 mL；176 mL：R1：4×35 mL，R2：2×18 mL；200 mL：R1：4×40 mL，R2：2×20 mL；300 mL：R1：4×60 mL，R2：2×30 mL；304 mL：R1：6×40 mL，R2：2×32 mL；438 mL：R1：6×57 mL，R2：3×32 mL；625 mL：R1：2×250 mL，R2：1×125 mL。	粤械注准 20172400988
9	全自动血液细胞分析仪 Auto Hematology Analyzer	BC-7500[B] CRP、BC-7500[N] CRP、BC-7500[R] CRP、BC-7500[NR] CRP BC-7500[B] CRP、BC-7500[N] CRP、BC-7500[R] CRP、BC-7500[NR] CRP	粤械注准 20202220342
10	糖化血红蛋白校准品 Hemoglobin A1c Calibrator	型号：CAL；规格：CAL-1:2mL×1 CAL-2:2mL×1；CAL-1:2mL×3 CAL-2:2mL×3	粤械注准 20152400532

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		CAL；CAL-1:2mL×1 CAL-2:2mL×1；CAL-1:2mL×3 CAL-2:2mL×3	
11	呼吸机 Ventilator	SynoVent E3、SynoVent B3、SynoVent E5、SynoVent B5 SynoVent E3、SynoVent B3、SynoVent E5、SynoVent B5	国械注准 20153080701
12	HLA-B27 检测试剂(流式细胞法) HLA-B27 Reagent	50 人份/盒 50tests	国械注准 20193401547
13	糖化血红蛋白质控品 HemoglobinA1c Control	型号:CRL;规格:CRL-1:2mL×1 CRL-2:2mL×1；CRL-1:2mL×3 CRL-2:2mL×3；CRL-1:2mL×1；CRL-2:2mL×1 CRL CRL-1:2mL×1 CRL-2:2mL×1；CRL-1:2mL×3 CRL-2:2mL×3；CRL-1:2mL×1 CRL-2:2mL×1	粤械注准 20152400531
14	血管紧张素转换酶（ACE）测定试剂盒（酶比色法） Angiotensin Converting Enzyme Kit (Enzymatic Colorimetric Assay Method)	R: 1×20 mL；R: 1×40 mL；R: 1×74 mL；R: 2×40 mL；R: 1×80 mL；R: 1×20 mL + Cal: 1×1 mL；R: 1×40 mL + Cal: 1×1 mL；R: 1×74 mL + Cal: 1×1 mL；R: 2×40 mL + Cal: 1×1 mL；R: 1×80 mL + Cal: 1×1 mL R: 1×20 mL；R: 1×40 mL；R: 1×74 mL；R: 2×40 mL；R: 1×80 mL；R: 1×20 mL + Cal: 1×1 mL；R: 1×40 mL + Cal: 1×1 mL；R: 1×74 mL + Cal: 1×1 mL；R: 2×40 mL + Cal: 1×1 mL；R: 1×80 mL + Cal: 1×1 mL	粤械注准 20152401373
15	彩色多普勒超声系统 Diagnostic Ultrasound System	DC-40、DC-40T、DC-40S、DC-40 Pro、DC-40 Exp、DC-41、DC-42、DC-43、DC-44、DC-45 DC-40、DC-40T、DC-40S、DC-40 Pro、DC-40 Exp、DC-41、DC-42、DC-43、DC-44、DC-45	粤械注准 20162061184
16	彩色多普勒超声诊断系统 Ultrasound System	ViewMate，ZS3 CV，ZS3 ICE，ZS3 Cath，ZS3 Elite ViewMate，ZS3 CV，ZS3 ICE，ZS3 Cath，ZS3 Elite	国械注准 20213061006
17	不饱和铁结合力质控品 UIBC Control	1 × 5 mL 1 × 5 mL	粤械注准 20152401376
18	不饱和铁结合力（UIBC）测定试剂盒（比色法） Unsaturated Iron Binding Capacity Kit (Colorimetric Method)	R1：1×20 mL + R2: 1×7 mL + Cal: 1×1 mL；54 mL：R1: 1×40 mL + R2: 1×13 mL + Cal: 1×1 mL；105 mL：R1: 4×20 mL + R2: 2×12 mL + Cal: 1×1 mL；157 mL：R1: 2×60 mL + R2: 2×18 mL + Cal: 1×1 mL；265 mL：R1: 3×70 mL + R2: 3×18 mL + Cal: 1×1 mL；281 mL：R1: 4×54 mL + R2: 4×16 mL + Cal: 1×1 mL；290	粤械注准 20152401375

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		mL：R1: 3×75 mL + R2: 2×32 mL + Cal: 1×1 mL；313 mL：R1: 4×60 mL + R2: 4×18 mL + Cal: 1×1 mL R1：1×20 mL + R2: 1×7 mL + Cal: 1×1 mL；54 mL：R1: 1×40 mL + R2: 1×13 mL + Cal: 1×1 mL；105 mL：R1: 4×20 mL + R2: 2×12 mL + Cal: 1×1 mL；157 mL：R1: 2×60 mL + R2: 2×18 mL + Cal: 1×1 mL；265 mL：R1: 3×70 mL + R2: 3×18 mL + Cal: 1×1 mL；281 mL：R1: 4×54 mL + R2: 4×16 mL + Cal: 1×1 mL；290 mL：R1: 3×75 mL + R2: 2×32 mL + Cal: 1×1 mL；313 mL：R1: 4×60 mL + R2: 4×18 mL + Cal: 1×1 mL	
19	CD3/CD8/CD45/CD4 检测试剂(流式细胞法-FITC/PE/PerCP/APC) CD3-FITC/CD8-PE/CD45-PerCP/CD4-APC Reagent	50 人份/盒 50tests	国械注准 20193401559
20	血细胞分析仪用校准物 HEMATOLOGY CALIBRATOR	型号：SC-CAL RET 包装规格：3mL×1、3mL×6 SC-CAL RET3mL×1、3mL×6	粤械注准 20202400379
21	尿酸（UA）测定试剂盒（尿酸酶—过氧化物酶法） Uric Acid Kit (Uricase-Peroxidase Method)	35 mL R1：1×25 mL，R2：1×10 mL；176mL R1：4×35 mL，R2：2×18 mL；200 mL R1：4×40 mL，R2：2×20 mL；300 mL R1：4×60 mL，R2：2×30 mL；304 mL R1：6×40 mL，R2：2×32 mL；310 mL R1：3×80 mL，R2：2×35 mL；438 mL R1：6×57 mL，R2：:3×32 mL；456 mL R1：6×60 mL，R2：3×32 mL；625 mL R1：2×250 mL，R2：1×125 mL；校准品规格（选配）：1×0.8 mL、1×1.0 mL、1×1.5 mL、1×1.8 mL 35 mL R1：1×25 mL，R2：1×10 mL；176mL R1：4×35 mL，R2：2×18 mL；200 mL R1：4×40 mL，R2：2×20 mL；300 mL R1：4×60 mL，R2：2×30 mL；304 mL R1：6×40 mL，R2：2×32 mL；310 mL R1：3×80 mL，R2：2×35 mL；438 mL R1：6×57 mL，R2：:3×32 mL；456 mL R1：6×60 mL，R2：3×32 mL；625 mL R1：2×250 mL，R2：1×125 mL；calibrator：1×0.8 mL、1×1.0 mL、1×1.5 mL、1×1.8 mL	粤械注准 20152400324
22	D—二聚体（D—Dimer）测定试剂盒（胶乳增强免疫透射比浊法） D-Dimer Kit (Particle-enhanced Immunoturbidimetric Assay Method)	R1: 1×17 mL + R2: 1×8 mL，R1: 1×30 mL + R2: 1×13 mL，R1: 1×40 mL + R2: 1×15 mL，R1: 1×45 mL + R2: 1×17 mL，R1: 1×50 mL + R2: 1×17 mL，R1: 1×17 mL + R2: 1×8 mL + Cal: 6×0.5 mL，R1: 1×30 mL + R2: 1×13 mL + Cal: 6×0.5 mL，R1: 1×40	粤械注准 20152401379

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		mL + R2: 1×15 mL + Cal: 6×0.5 mL，R1: 1×45 mL + R2: 1×17 mL + Cal: 6×0.5 mL，R1: 1×50 mL + R2: 1×17 mL + Cal: 6×0.5 mL R1: 1×17 mL + R2: 1×8 mL，R1: 1×30 mL + R2: 1×13 mL，R1: 1×40 mL + R2: 1×15 mL，R1: 1×45 mL + R2: 1×17 mL，R1: 1×50 mL + R2: 1×17 mL，R1: 1×17 mL + R2: 1×8 mL + Cal: 6×0.5 mL，R1: 1×30 mL + R2: 1×13 mL + Cal: 6×0.5 mL，R1: 1×40 mL + R2: 1×15 mL + Cal: 6×0.5 mL，R1: 1×45 mL + R2: 1×17 mL + Cal: 6×0.5 mL，R1: 1×50 mL + R2: 1×17 mL + Cal: 6×0.5 mL	
23	葡萄糖（Glu）测定试剂盒（葡萄糖氧化酶法） Glucose Kit (GOD-POD Method)	35 mL R1：1×25 mL，R2：1×10 mL；176 mL R1：4×35 mL，R2：2×18 mL；200 mL R1：4×40 mL，R2：2×20 mL；300 mL R1：4×60 mL，R2：2×30 mL；310 mL R1：3×80 mL，R2：2×35 mL；438 mL R1：6×57 mL，R2：3×32 mL；456 mL R1：6×60 mL，R2：3×32 mL；625 mL R1：2×250 mL，R2：1×125 mL；校准品规格（选配）：1×0.8 mL、1×1.0 mL、1×1.5 mL、1×1.8 mL 35mL R1：1×25mL，R2：1×10mL；176mL R1：4×35mL，R2：2×18mL；200mL R1：4×40mL，R2：2×20mL；300mL R1：4×60mL，R2：2×30mL；310mL R1：3×80mL，R2：2×35mL；438mL R1：6×57mL，R2：3×32mL；456mL R1：6×60mL，R2：3×32mL；625mL R1：2×250mL，R2：1×125mL；calibrator：1×0.8mL、1×1.0mL、1×1.5mL、1×1.8mL	粤械注准 20152400329
24	总胆红素（T—bil）测定试剂盒（重氮盐法） Bilirubin Total Kit (DSA Method)	35 mL R1：1×25 mL，R2：1×10 mL；90 mL R1：4×18 mL，R2：1×18 mL；100 mL R1：4×20 mL，R2：1×20 mL；160 mL R1：4×32 mL，R2：4 × 8 mL；180 mL R1：3×48 mL，R2：3×12 mL；240 mL R1：4×48 mL，R2：4×12 mL；625 mL R1：2×250 mL，R2：1×125 mL 35 mL R1：1×25 mL，R2：1×10 mL；90 mL R1：4×18 mL，R2：1×18 mL；100 mL R1：4×20 mL，R2：1×20 mL；160 mL R1：4×32 mL，R2：4 × 8 mL；180 mL R1：3×48 mL，R2：3×12 mL；240 mL R1：4×48 mL，R2：4×12 mL；	粤械注准 20152400326

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		625 mL R1：2×250 mL，R2：1×125 mL	
25	胰岛素校准品 Insulin Calibrators	C0：1×2.0 mL，C1：1×2.0 mL，C2：1×2.0 mL C0：1×2.0 mL，C1：1×2.0 mL，C2：1×2.0 mL	粤械注准 20152400887
26	甲状腺球蛋白抗体（Anti—Tg）测定试剂盒（化学发光免疫分析法） Antibody to thyroglobulin(CLIA)	2×30 人份/盒、2×50 人份/盒、2×100 人份/盒 2×30tests、2×50tests、2×100tests	粤械注准 20152400843
27	游离 β—人绒毛膜促性腺激素（Free β—hCG）测定试剂盒（化学发光免疫分析法） Free β Human Chorionic Gonadotropin(CLIA)	2×50 人份/盒、2×100 人份/盒 2×50tests、2×100tests	粤械注准 20192400167
28	抗甲状腺过氧化物酶抗体（Anti—TPO）测定试剂盒（化学发光免疫分析法） Antibody to thyroid peroxidase(CLIA)	2×30 人份/盒、2×50 人份/盒、2×100 人份/盒 2×30tests、2×50tests、2×100tests	粤械注准 20152400845
29	尿微量白蛋白质控品 MALB Control	1 × 1 mL 1 × 1 mL	粤械注准 20152401377
30	生殖激素类复合定值质控品 Reproductive Multi Control	低值：6×5.0 mL，12×5.0 mL，1×5.0 mL，3×5.0 mL；高值：6×5.0 mL，12×5.0 mL，1×5.0 mL，3×5.0 mL。 L：6×5.0 mL、12×5.0 mL、1×5.0 mL、3×5.0 mL;H：6×5.0 mL、12×5.0 mL、1×5.0 mL、3×5.0 mL	粤械注准 20162400686
31	便携式彩色多普勒超声系统 Diagnostic Ultrasound System	M8，M8 Super，M9T M8，M8 Super，M9T	粤械注准 20162060988
32	流式细胞仪 Flow Cytometer	BriCyte E6 BriCyte E6	粤械注准 20142220183
33	全自动血液细胞分析仪 Auto Hematology Analyzer	BC-5300、BC-5100 BC-5300、BC-5100	粤械注准 20152220359
34	5′—核苷酸酶（5′—NT）测定试剂盒（酶比色法） 5'-Nucleotidase Kit (Enzymatic Colorimetric Method)	30 mL R1：1×20 mL，R2：1×10 mL； 54 mL R1：1×36 mL，R2：1×18 mL； 60 mL R1：1×40 mL，R2：1×20 mL； 90 mL R1：1×60 mL，R2：1×30 mL； 100 mL R1：2×32 mL，R2：2×18 mL； 108 mL R1：2×36 mL，R2：2×18	粤械注准 20152400328

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		mL； 300 mL R1：1×200 mL，R2：1×100 mL； 校准品（选配）：1×1.0 mL。 30 mL R1：1×20 mL，R2：1×10 mL； 54 mL R1：1×36 mL，R2：1×18 mL； 60 mL R1：1×40 mL，R2：1×20 mL； 90 mL R1：1×60 mL，R2：1×30 mL； 100 mL R1：2×32 mL，R2：2×18 mL； 108 mL R1：2×36 mL，R2：2×18 mL； 300 mL R1：1×200 mL，R2：1×100 mL； calibrator:1×1.0 mL。	
35	便携式彩色多普勒超声系统 Diagnostic Ultrasound System	TE7，TE7T，TE7S，TE7 Pro，TE7 Super，TE5，TE5T，TE5S，TE5 Pro，TE5 Super TE7，TE7T，TE7S，TE7 Pro，TE7 Super，TE5，TE5T，TE5S，TE5 Pro，TE5 Super	粤械注准 20192060544
36	甲状腺功能复合定值质控品 Thyroid Function Multi Control	低值：1×5.0 mL、3×5.0 mL、6×5.0 mL、12×5.0 mL；高值：1×5.0 mL、3×5.0 mL、6×5.0 mL、12×5.0 mL L：1×5.0 mL、3×5.0 mL、6×5.0 mL、12×5.0 mL;H：1×5.0 mL、3×5.0 mL、6×5.0 mL、12×5.0 mL	粤械注准 20152400877
37	血管紧张素转换酶质控品 ACE Control	低值：1 × 1 mL；高值：1 × 1 mL 1×2levels×1mL	粤械注准 20152401383
38	转铁蛋白质控品 TRF Control	低值：1 × 1 mL；高值：1 × 1 mL L：1×1mL；H：1×1mL	粤械注准 20152401384
39	D—二聚体质控品 D-Dimer Control	低值：1 × 0.5 mL；高值：1 × 0.5 mL L：1×0.5mL；H：1×0.5mL	粤械注准 20152401369
40	全数字便携式超声诊断系统 Digital ultrasonic diagnostic imaging system	DP-20、DP-20T、DP-21、DP-25、DP-28 DP-20、DP-20T、DP-21、DP-25、DP-28	粤械注准 20142060191
41	除颤监护仪 Automated External Defibrillator	BeneHeart D6，BeneHeart D5，BeneHeart D3，BeneHeart D2，BeneHeart D1 BeneHeart D6，BeneHeart D5，BeneHeart D3，BeneHeart	国械注准 20173080600

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
		D2，BeneHeart D1	
42	彩色多普勒超声系统 Diagnostic Ultrasound System	a）DC-N3 b）DC-N3T c）DC-N3S d) DC-N3 PRO a）DC-N3 b）DC-N3T c）DC-N3S d) DC-N3 PRO	粤械注准 20172061327
43	便携式彩色多普勒超声系统 Diagnostic Ultrasound System	M9、M9CV、M9 Pro、M9 Super M9、M9CV、M9 Pro、M9 Super	国械注准 20193061691
44	β—羟丁酸质控品 β-HB Control	低值：1 × 5 mL；高值：1 × 5 mL L：1×5mL；H：1×5mL	粤械注准 20152401380
45	全数字便携式超声诊断系统 Portable Diagnostic Ultrasound System	DP-10、DP-10T、DP-11、DP-15、DP-18 DP-10、DP-10T、DP-11、DP-15、DP-18	粤械注准 20142060189
46	尿液分析仪 Urine Analyzer	UA-600、UA-600T、UA-66 UA-600、UA-600T、UA-66	粤械注准 20192220390
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