AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

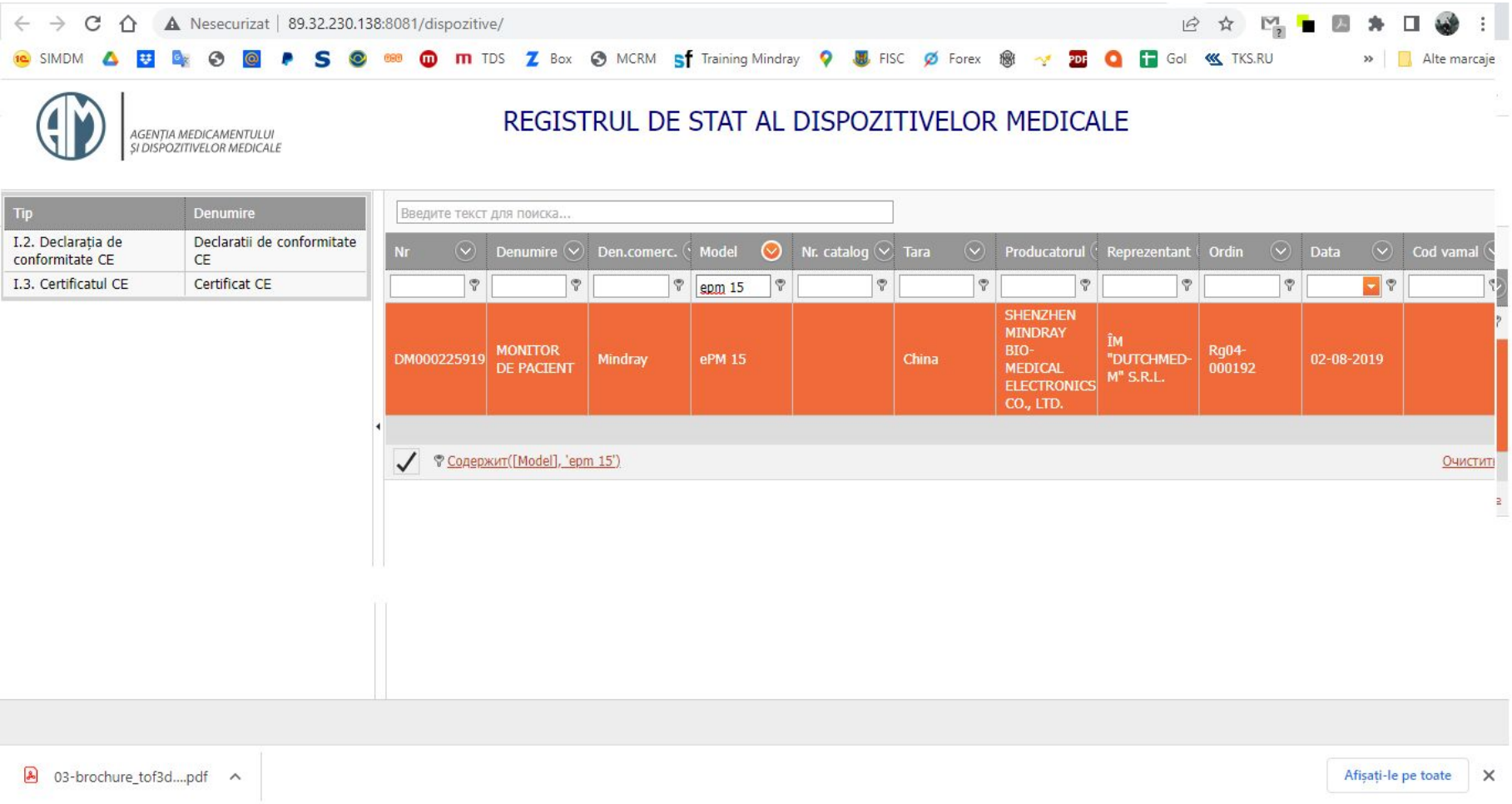
Tip	Denumire
I.3. Certificatul CE	Certificat CE
I.2. Declarația de conformitate CE	Declaratii de conformitate CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			WATO EX-65 PRO							
DM000153166	Unitate de anestezie	Mindray	WATO EX-65 Pro		China	SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.	ÎM "DUTCHMED-M" S.R.L.	A07.PS-01.Rg04-276	01-10-2018	

Содержит([Model], 'WATO EX-65 PRO') Очистить

Digitally signed by Prodan Sveatoslav
Date: 2022.12.14 10:29:32 EET
Reason: MoldSign Signature
Location: Moldova


Nesecurizat | 89.32.230.138:8081/dispozitive/
SIMDM TDS Box MCRM Training Mindray FISC Forex Gol TKS.RU Alte marcaje
AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE
REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE
Tip
Denumire
I.2. Declarația de conformitate CE
Declaratii de conformitate CE
I.3. Certificatul CE
Certificat CE
Введите текст для поиска...
Nr
Denumire
Den.comerc.
Model
Nr. catalog
Tara
Producatorul
Reprezentant
Ordin
Data
Cod vamal
epm 15
DM000225919
MONITOR DE PACIENT
Mindray
ePM 15
China
SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
ÎM "DUTCHMED-M" S.R.L.
Rg04-000192
02-08-2019
Содержит([Model], 'epm 15')
Очистить
03-brochure_tof3d....pdf
Afișați-le pe toate

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

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

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

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

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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:

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
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

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

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Deutsche
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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www.zlg.de
ZLG-BS-244.10.08

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

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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A4 / 07.17

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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

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

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ZLG-BS-244.10.08

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 0165 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): Anesthesia Machine

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

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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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 0165 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

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

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Declaration of Conformity-V4.0

CE 0123

Declaration of Conformity

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

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

Product: Anesthesia System (Including Accessories)

Model: **WATO EX-55 Pro、WATO EX-65 Pro**

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

Conformity Assessment Route: MDD Annex IIexcluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for 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: **2016-7-13**

Place, Date of Issue: Shenzhen, 2020.12.31

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Applied Standards List

Product: **Anesthesia System**

Model: **WATO EX-55 Pro、WATO EX-65 Pro**

Applied Standards:

EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN 60601-1: 2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN ISO 80601-2-13:2012/A2:2019	Medical electrical equipment Part 2-13:Particular requirements for basic and essential performance of an anesthetic workstation
EN ISO 80601-2-55:2018	Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
IEC 60601-2-10:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
EN 60601-2-26:2015	Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs
EN ISO 10079-3:2014	Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source
EN ISO 5359:2014/A1:2017	Low-pressure hose assemblies for use with medical gases

EN ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets
EN ISO 5360:2016	Anaesthetic vaporizers - Agent-specific filling systems
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN 62304:2006/A1:2015	Medical device software - Software life cycle processes.
EN 60601-1-6:2010/A1:2015	Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-1-8:2007/A1:2017	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

Declaration of Conformity V3.0

CE

Declaration of Conformity

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, High-tech Industrial Park, Nanshan,Shenzhen,518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	Anesthesia System (Including Accessories)
Model:	WATO EX-55 Pro、 WATO EX-65 Pro

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 2011/65/EU. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

EN 50581:2012.

Start of CE-Marking: **2016-7-13**

Place, Date of Issue: Shenzhen, 2020.12.31

Signature: .....

Name of Authorized Signatory: Mr. Wang Xinbing

Position Held in Company: Manager, Technical Regulation

Declaration of Conformity-V1.0

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:	Patient Monitor (Including Accessories)
Model:	ePM 10/ePM 10A/ePM 10C/ePM 12/ePM 12A/ePM 12C/ ePM 15/ePM 15A/ePM 15C
Classification:	Ⅱb（According to Rule 10 of MDD Annex Ⅸ）
Conformity Assessment Route:	MDD Annex Ⅱ excluding (4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for 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:	**2018-12-29**
Place, Date of Issue:	Shenzhen，2018.12.29
Signature:	
Name of Authorized Signatory:	Mr. Wang Xinbing
Position Held in Company:	Manager, Technical Regulation

Product:	Patient Monitor (Including Accessories)
Model:	ePM 10/ePM 10A/ePM 10C/ePM 12/ePM 12A/ePM 12C/ ePM 15/ePM 15A/ePM 15C

Applied Standards:

EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN ISO 10993-1:2009/AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and and skin sensitization
EN 60601-1: 2006+A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2013	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 60601-1-8:2012	edical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs

IEC 60601-2-27:2011	Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30:2013	Medical electrical equipment -- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011	Medical electrical equipment - Part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
IEC 60601-2-49:2011	Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
ISO 80601-2-55:2011	Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
ISO 80601-2-56:2009	Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical electrical equipment Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 81060-2:2013	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
IEC 62366-1:2015	Medical devices Part 1: Application of usability engineering to medical devices
IEC 62304:2015	Medical device software - Software life cycle processes

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www.zlg.de
ZLG-BS-244.10.08

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 104938 0002 Rev. 01

Manufacturer:

MIPM Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Str. 6
82291 Mammendorf
GERMANY

Facility(ies):

MIPM Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Str. 6, 82291 Mammendorf, GERMANY

Product Category(ies):

Equipment used during investigation in magnetic resonance imaging and for measuring systems including the determination of physiological pressures.
Physiological Monitoring Systems

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.: 713162466

Valid from: 2019-11-01
Valid until: 2024-05-10

Date, 2019-10-31

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

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

Product Service

Certificate

No. Q5 104938 0001 Rev. 00

Holder of Certificate: **MIPM Mammendorfer Institut für Physik und Medizin GmbH**
Oskar-von-Miller-Str. 6
82291 Mammendorf
GERMANY

Facility(ies): MIPM Mammendorfer Institut für Physik und Medizin GmbH
Oskar-von-Miller-Str. 6, 82291 Mammendorf, GERMANY

Certification Mark:

Scope of Certificate: **Design and development, manufacture, sales and service of electronic equipment used during investigations in magnetic resonance imaging and measurement systems including probes for the determination of physiological pressure and servicing in medical technology**

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

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.: 713162466

Valid from: 2019-11-01
Valid until: 2023-05-10

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

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