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: 2023.04.14 19:26:47 EEST
Reason: MoldSign Signature
Location: Moldova

Nesecurizat | 89.32.230.138:8081/dispozitive/

SIMDM TDS Box MCRM Training Mindray FISC Forex TKS.RU Gol 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

TÜV SÜD 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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Manager, US Certification Body,
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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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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

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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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A4 / 07.17

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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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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

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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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

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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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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 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

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

TÜV®

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
			tof				dutchmed			
DM000436518	SISTEM PENTRU MONITORIZARE BLOCULUI NEUROMUSCULA		TOF 3D	2510091	Germania	MIPM MAMMENDORFE INSTITUT FÜR PHYSIK UND MEDIZIN GMBH.	ÎM "DUTCHMED-M" S.R.L.	Rg04-000041	24-02-2023	

Содержит([Model], 'tof') И Содержит([Reprezentant], 'dutchmed') Очистить

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
268639-2018-AQ-CZS-RvA-CC1

Valid:
26 November 2021 – 25 November 2024

Belongs to Central Office Certificate No.:
268639-2018-AQ-CZS-RvA

This is to certify that the management system of

EKOM spol. s r. o.
Division Compressor
Priemyselná 5031/18, 921 01 Piešťany, Slovak Republic

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

Design and development, manufacture and sales of oil free compressors for industrial use.

Place and date:
Praha, 08 October 2021

For the issuing office:
DNV - Business Assurance
Thákurova 4, 160 00 Praha, Czech Republic

Mária Lichnerová
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
282055-2019-AQ-CZS-Norwegian Accreditation

Initial certification date:
30 January 2019

Valid:
31 January 2022 – 30 January 2025

This is to certify that the management system of

EKOM spol. s.r.o.

Priemyselná 5031/18, 921 01 Piešťany, Slovak Republic

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, manufacture and sale of suction systems, oil free compressors with or without drying and filtration systems for medical use.

Place and date:
Høvik, 03 December 2021

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9904-2017-CE-CZS-NA-PS rev.2.0	PRJC-89738-2008-PRC-SVK	27 May 2024

This is to certify that the quality system of:

EKOM spol. s r.o.

Priemyselná 5031/18, 921 01 Piešťany, Slovak Republic

For design, production and final product inspection/testing of:

MEDICAL COMPRESSORS

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 01 February 2021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Sholeh Gheissar

Sholeh Gheissar

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB0434) certificate No. 106326-2011-CE-CZS-NA following transfer of notified body function to DNV Nemko Presafe AS (NB2460) at recertification	2017-05-22
1.0	Exclusion of DK50 D, DK50 DM from certificate Extension in scope -new products (in bold) added	2020-04-01
2.0	**Re-certification**	**2021-02-01**

Products covered by this Certificate:

Product Description	Product Name	Class
Medical compressors	DK50 DS DK50 DE DK50 DI AIR-550	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
EKOM spol. s r. o.	Priemyselná 5031/18, 921 01 Piešťany, Slovak Republic

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate