Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 032913 0039 Rev. 00

Manufacturer:
Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road
Shipu Science and Technology Park, Xiangshan
315731 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road, Shipu Science and Technology Park,
Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Infant Incubator, Transport Incubator, Infant Radiant Warmer, Neonate Bilirubin Phototherapy Equipment, Infant T-piece Resuscitator

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.: SH19011EXT01

Valid from: 2019-10-10
Valid until: 2024-05-26

Date, 2019-10-10

Digitally signed by Trocin Caterina
Date: 2020.05.23 19:12:09 GMT+03:00
Reason: MoldSign Signature
Location: Moldova

Stefan Preiß
Head of Certification/Notified Body

REPUBLICA MOLDOVA, mun. CHIȘINĂU «HEALTH MEDICAL SOLUTIONS» S.R.L. IDNO 1018600009625

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

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

TÜV®

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

TÜV SÜD
Product Service

Certificate

No. Q5 032913 0038 Rev. 00

Holder of Certificate: **Ningbo David Medical Device Co., Ltd.**
No.2, Keyuan Road
Shipu Science and Technology Park, Xiangshan
315731 Ningbo, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Ningbo David Medical Device Co., Ltd.
No.2, Keyuan Road, Shipu Science and Technology Park,
Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: Design and Development,
Production and Distribution of Infant Incubator,
Transport Incubator, Infant Radiant Warmer,
Neonate Bilirubin Phototherapy Equipment,
Far-Infrared Radiant Heater, Low-Pressure Aspirator,
Breath Resuscitation Bag, Infant Non-contact Oxygen Hood,
Infant Bed, Infant Head Fixing Unit,
Medical Air/Oxygen Blender,
Infant T-piece Resuscitator

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.: SH1901124

Valid from: 2019-06-27
Valid until: 2022-05-31

REPUBLICA MOLDOVA, mun. CHIȘINĂU «HEALTH MEDICAL SOLUTIONS» S.R.L. IDNO 1018600009625 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Date, 2019-06-27

Stefan Preiß
Head of Certification/Notified Body

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A4 / 07.17

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

TÜV SÜD Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Panasonic Electric Works Europe AG

Robert-Koch-Str. 100
85521 Ottobrunn
Germany

has established and applies
a Quality Management System for

Sales of electromechanical and electronic components, Industrial Automation Products and associated Software, Home Appliances and Photovoltaic Panels Development of Industrial Automation Products and associated Software.

An audit was performed, Report No. **707079632**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2018-04-27** until **2021-04-26**.

Certificate Registration No.: **12 100 55384 TMS**.

Product Compliance Management
Munich, 2018-02-22

IAF DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS01-07/10

PERRY JOHNSON REGISTRARS, INC.

Certificate of Registration

Perry Johnson Registrars, Inc., has audited the Quality Management System of:

USOC MEDICAL
20 Morgan, Irvine, CA 92618 United States

(Hereinafter called the Organization) and hereby declares that Organization is in conformance with:

ISO 9001:2015

This Registration is in respect to the following scope:

Refurbishing, Purchasing and Sale of various Biomedical Devices for the Healthcare Industry

This Registration is granted subject to the system rules governing the Registration referred to above, and the Organization hereby covenants with the Assessment body duty to observe and comply with the said rules.

Terry Boboige

Terry Boboige, President
Perry Johnson Registrars, Inc. (PJR)
755 West Big Beaver Road, Suite 1340
Troy, Michigan 48084
(248) 358-3388

PERRY JOHNSON REGISTRARS, INC.

UKAS MANAGEMENT SYSTEMS 0155

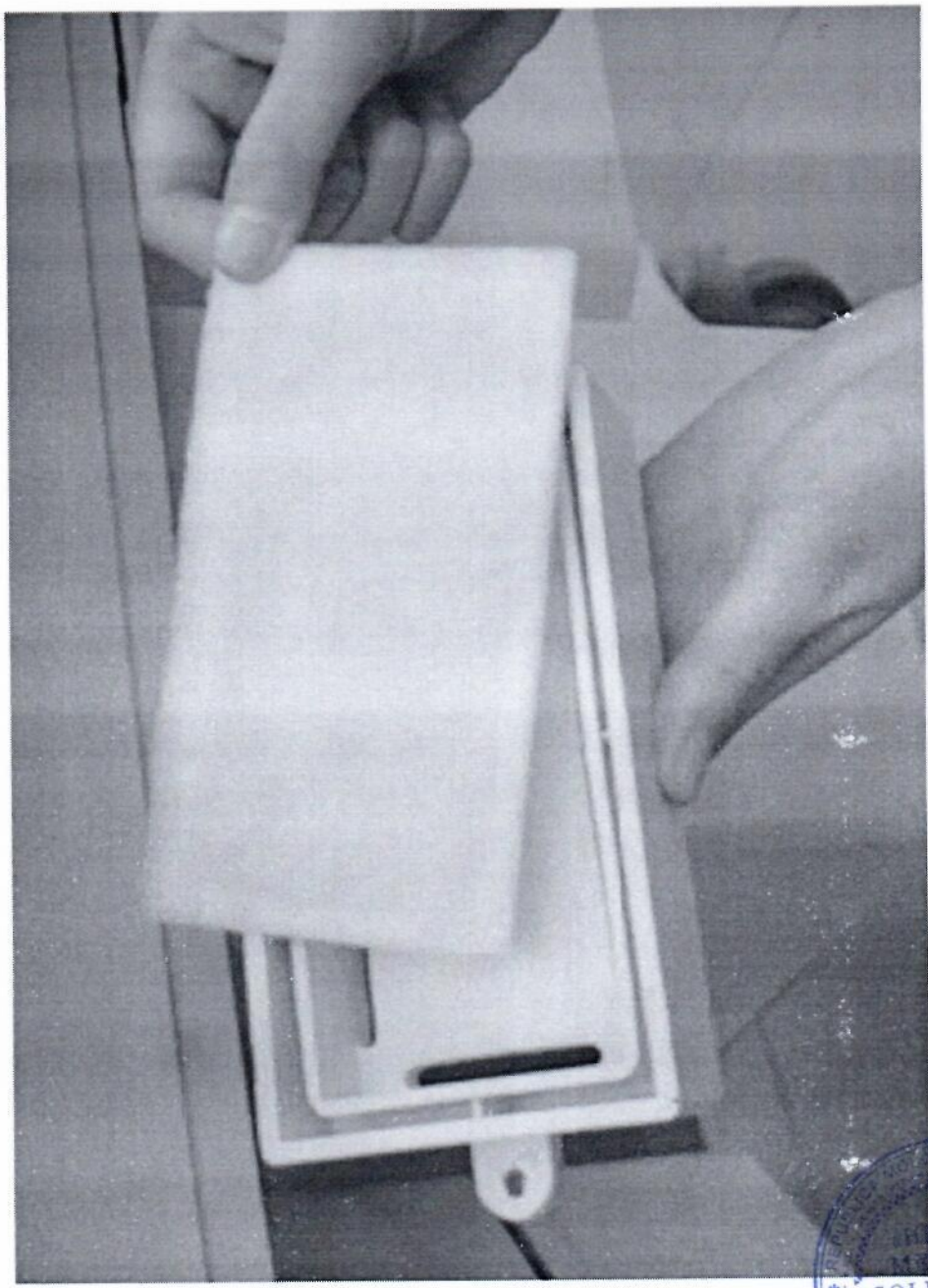
ANAB ACCREDITED ISO/IEC 17021 MANAGEMENT SYSTEMS CERTIFICATION BODY

«HEALTH MEDICAL SOLUTIONS» S.R.L.

The use of the UKAS accreditation symbol is in respect to the activities covered by the Accreditation Certificate Number 0155

The validity of this certificate is dependent upon ongoing surveillance.

Effective Date:	Expiration Date:	
April 1, 2019	March 31, 2022	C2019-01029



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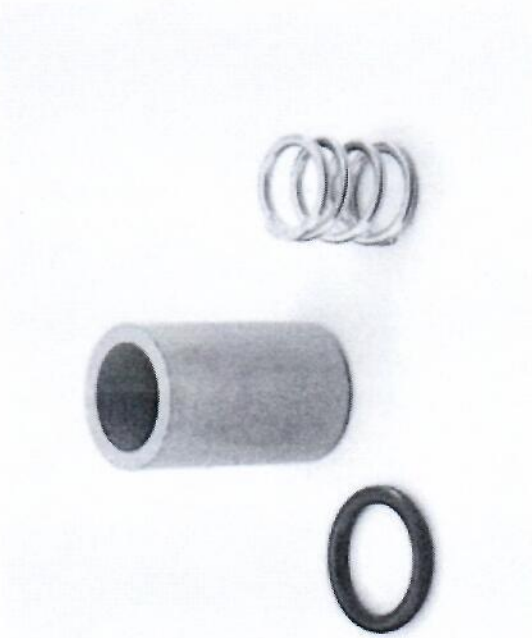
«HEALTH MEDICAL SOLUTIONS» S.R.L.
IDNO 1016600009625
SOCIETATEA CU RĂSPUNDERE LIMITATĂ



REPUBLICA MOLDOVA, mun. CHIȘINĂU
«HEALTH MEDICAL SOLUTIONS» S.R.L.
IDNO 1018600009625
SOCIETATEA CU RĂSPUNDERE LIMITATĂ