Digitally signed by Lungu Ion
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Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. 59 din 19.08.2024

Solicitantul **"Health Medical Solutions" SRL**, cu sediul Republica Moldova, MD-2019, mun. Chişinău, str. Grenoble 128, of. 011, tel./fax: +373 79627404, +373 60556955, e-mail: info@hms.md, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale, clasa de risc **IIb**, pentru introducerea şi punerea la dispoziţie pe piaţă a:

1. **INCUBATOR NEONATAL DE TRASPORT**, denumirea comercială – **DAVID MEDICAL**, model – **TI-2000,** producător – NINGBO DAVID MEDICAL DEVICE CO., LTD., ţara de origine – China, etc.;
   ...
2. **INCUBATOR NEONATAL**, denumirea comercială – **DAVID MEDICAL**, model – **YP-500,** producător – NINGBO DAVID MEDICAL DEVICE CO., LTD., ţara de origine – China, etc.;
   ...
3. Lista se anexeaza (conf. Listei din formularul Excell);

Se anexează următoarele acte:
1. EC Certificat No. G1 032913 0043 Rev.00 din 23.03.2021;
2. Confirmation Statement No. GCQ 032913 0047 Rev. 00 din 09.10.2023;
3. NB Confirmation Letter CL 032913 0049 Rev.00 din 08.04.2024;
4. Manufacturers Ningbo David Medical Device Co. Ltd. Declaration;
5. EC Declaraţie de conformitate (Electrotherapy nerve/muscle stimulators) din 05.06.2024;
6. Document de reprezentanta autorizata No L2024060 din 29.07.2024;
7. Lista dispozitivelor (formularul Excell).

Data 19.08.2024 Semnătura _____

Tabelul de recepţionare a notificării

(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	Accept ID 762120
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	nr 8918 din 20.08.2024
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	Valentina Balabaci
Semnătura persoanei responsabile	Şef secţie

AGENŢIA MEDICAMENTULUI ŞI DISPOZITIVELOR MEDICALE
MD-2028, m.n.Chişinău, str. Korolenko, 2/1
GHIŞEUL UNIC
Nr. 20.08.2024

DAVID

Declaration of Conformity

Manufacturer: Ningbo David Medical Device Co.,Ltd

Address : No.2,Keyuan Road, Shipu Science and Technology Park,Xiangshan315731
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,Xiangshan315731
Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp.GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg Germany

Product Category: Infant Incubator

Model: YP-2000
YP-3000 Series (including YP-3000 and YP-2008)
YP-970 Series(including YP-910, YP-920, YP-930 and YP-970)
YP-90 Series(including YP-90, YP-90A, YP-90B, YP-90AB and YP-90AC)
YP-100 Series (including YP-100, YP-100A, YP-100B and YP-100AB)
YP-500 Series (including YP-500 and YP-500A)
YP-600 Series (including YP-600, YP-600A, YP-600B YP-600C and YP-600D)
YP-700 Series (including YP-700, YP-700A, YP-700B YP-700C and YP-700D)
YP-800 Series (including YP-800, YP-800A, YP-800B and YP-800C)
YP-2100 Series (including YP-2100, YP-2100A and YP-2100B)
YP-2200 Series (including YP-2200, YP-2200A and YP-2200B)
YP-2500 Series (including YP-2500, YP-2500A and YP-2500B)
YP-2800 Series (including YP-2800, YP-2800A and YP-2800B)
YP-3100 Series (including YP-3100, YP-3100A and YP-3100B)

Classification:class IIb, based on MDD 93/42/EEC annex IX Rule 9

The GMDNS Code: 36025

Conformity Assessment Route:Annex **II.3** of MDD 93/42/EEC

We declare that compliance of the above medical device with the applicable requirements of Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC. All the supporting documents and files are retained under the premises of the manufacturer. We are exclusively responsible for the documents.

Notified Body: TÜV SÜD Product Sevice GmbH , Zertifizierstelle，Ridlerstrasse 65,80339 MÜnchen, Germany

Identification Number: 0123

Declaration Conformity of Infant Incubator
(CE Technical File_Part A)

Certificate No.: G1 032913 0043 Rev.00

Expire date of the Certificate: 2024-05-26

Confirmation Statement Certificate No.: GCQ 032913 0047 Rev.00

Start of CE-Marking: 2003-01-01

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates), *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met, *and*
- the **device(s)** listed above and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service.

End date of extended validity / transition period: 2028-12-31

Confirmation Letter No.: CL 032913 0049 Rev. 00

Signature:

Name: Mr.Dingyu Lin

Position: Person Responsible for Regulatory Compliance

Place, Date of Issue: Xiangshan, Ningbo, Zhejiang, 2024/05/27

CE 0123

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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 032913 0043 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

Product Category(ies):

Infant Incubator, Transport Incubator,
Infant Radiant Warmer,
Neonate Bilirubin Phototherapy Equipment,
Infant T-piece Resuscitator,
Medical Air/Oxygen Blender,
Medical Air Compressor, Patient Monitor,
Transcutaneous Jaundice Detector

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 032913 0043 Rev. 00

Report No.: SH2001102

Valid from: 2021-03-23
Valid until: 2024-05-26

Date, 2021-03-23

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

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 032913 0047 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

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):

G1 032913 0043 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 032913 0047 Rev. 00

Report No.: SH2301101

Valid until: 2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2023-10-09

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 032913 0047 Rev. 00

Product Category(ies): **Infant Incubator, Transport Incubator, Infant Radiant Warmer, Neonate Bilirubin Phototherapy Equipment, Infant T-piece Resuscitator, Medical Air/Oxygen Blender, Medical Air Compressor, Patient Monitor, Transcutaneous Jaundice Detector**

Description of Change:

Certificate Address changed from " No.2, Keyuan Road, Shipu Science and Technology Park, Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA" "No.35, Jinxing Road, Binhai Industrial Park, Xiangshan Economic Development Zone, 315712 Ningbo, Zhejiang, PEOPLE'S REPUBLIC OF CHINA" to " No.2, Keyuan Road, Shipu Science and Technology Park, Xiangshan, 315731 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA "

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

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

TÜV SÜD Product Service

Certificate

No. Q5 032913 0042 Rev. 02

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.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 Medical Air Compressor, Patient Monitor, Transcutaneous Jaundice Detector, Neonate Hypothermia Device, EEG Monitor

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 032913 0042 Rev. 02

Report No.: SH2301101

Valid from: 2023-10-09
Valid until: 2025-05-31

Date, 2023-10-09

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV SÜD Product Service

Certificate

No. Q5 032913 0042 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):

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

See Scope of Certificate

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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

Your reference/letter of	Our reference/name	E-mail	Tel. extension	Date	Page
032913	SH2401100_CL	Sicong.Yu@tuvsud.com	+86 21 6140 8600	2024-04-08	1 of 10

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 032913 0049 Rev. 00

Reference: 713296038 | SH2401100_CL

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: CN-MF-000009962

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below:

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see: www.tuvsud.com/ps-cert?q=cert:CL 032913 0049 Rev. 00

In case of inquiries please contact: medical_devices@tuvsud.com

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-04-08

TÜV SÜD Product Service GmbH
Medical and Health Services

Yu Sicong
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Konrad Fackler
Application Reviewer