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. **184** din **30.06.2023**

"Health Medical Solutions" SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011, E-mail: info@hms.md, srl.hms.moldova@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor **clasa de risc IIB, Anexa II**:

1. **Sistem radiografic digital (cu bucky vertical),** denumire comercială - **WDM**, model – **WDM New Oriental 1000ND**, producător- **Beijing Wandong Medical Technology Co., Ltd**, țara de origine - **China**;

Se anexează următoarele acte:

1. Împuternicirea de a reprezenta **Beijing Wandong Medical Technology Co., Ltd.**, **China** din 29.06.2023;
2. Certificat CE No.**G1043895 0011** din 12.01.2021 (valabil pînă la 19.12.2023);
3. Declarația de conformitate **Beijing Wandong Medical Technology Co., Ltd.**, din 12.01.2021;
4. Certificat ISO 13485:2016 No.**Q5 043895 0012** din 03.03.2022 (valabil pînă la 13.12.2024);
5. Declaraţie pe proprie răspundere.

Data **30.06.2023**

Semnătura Digitally signed by Lungu Ion
Date: 2023.06.30 13:10:53 EEST
Reason: MoldSign Signature
Location: Moldova

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care dețin marcajul CE
Către Agenția Medicamentului și Dispozitive Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

"Health Medical Solutions" SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011 E-mail: info@hms.md, srl.hms.moldova@gmail.com, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. **Sistem radiografic digital (cu bucky vertical),** denumire comercială - **WDM**, model – **WDM New Oriental 1000ND**, producător- **Beijing Wandong Medical Technology Co., Ltd**, țara de origine - **China**;

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura* _____
Lungu Ion, Administrator
+37379627404, +37369423432 Data 30.06.2023

Date: June 29, 2023

LETTER OF AUTHORIZATION

To Whom it May Concern,

We, **Beijing Wandong Medical Technology Co., Ltd.**, who are official manufacturer of Medical X-ray Systems, having headquarters at Building 3, No. 9, Jiuxianqiaodong Road, Chaoyang District, Beijing, 100015, China, assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Republic of Moldova, Chișinău, MD-2019, 128, Grenoble str., OF.011.

- as authorized representative in the Republic of Moldova in correspondence with the conditions of Directive 93/42/EEC.
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the in territory of Republic of Moldova, and to perform Essential Duties required by Law No. 102 on 09.06.2017 regarding Medical Devices.

This Authorization letter is valid until June 28, 2024.

Signed:

BEIJING WANDONG MEDICAL TECHNOLOGY CO., LTD.

Beijing Wandong Medical Technology Co., Ltd.
Address: Building 3, No.9, Jiuxianqiaodong Road, Chaoyang District, 100015, Beijing, P.R.China
Tel: +86 10 8457 5792/3/5 | Fax: +86 10 8457 5794
Email: international@wandong.com.cn | Web: www.wandong.com.cn

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

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 043895 0011 Rev. 02

Manufacturer:

Beijing Wandong Medical Technology Co., Ltd.
Building 3, No.9, Jiuxianqiaodong Road
Chaoyang District
100015 Beijing
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): **Interventional Angiography System, Digital Radiography and Fluoroscopy System, Mobile Digital Radiography X-ray System and Medical X-ray Radiographic 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. 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 043895 0011 Rev. 02

Report No.: BJ20012302

Valid from: 2021-01-12
Valid until: 2023-12-19

Date, 2021-01-12

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

TÜV®

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

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

TÜV SÜD Product Service

Certificate

No. Q5 043895 0012 Rev. 00

Holder of Certificate:

Beijing Wandong Medical Technology Co., Ltd.
Building 3, No.9, Jiuxianqiaodong Road
Chaoyang District
100015 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Beijing Wandong Medical Technology Co., Ltd.
Building 3, No.9, Jiuxianqiaodong Road, Chaoyang District,
100015 Beijing, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:

Scope of Certificate:

Design and Development, Production and Distribution, Installation and Service of Interventional Angiography System, Digital Radiography and Fluoroscopy System, Mobile Digital Radiography X-ray System and Medical X-ray Radiographic System.

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). 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 043895 0012 Rev. 00

Report No.: BJ21012302

Valid from: 2022-03-03
Valid until: 2024-12-13

Date, 2022-03-03

Christoph Dicks
Head of Certification/Notified Body

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

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DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER:	*BEIJING WANDONG MEDICAL TECHNOLOGY CO.,LTD.* Building 3, No.9, Jiuxianqiaodong Road, Chaoyang District, Beijing 100015, P.R.China
MEDICAL DEVICE:	*NEW ORIENTAL 1000ND* *MEDICAL X-RAY RADIOGRAPHIC SYSTEM*
CLASSIFICATION - ANNEX IX:	*CLASS II B*
GMDN CODE:	*37645*
CONFORMITY ASSESSMENT ROUTE:	*ANNEX II.3 EXCLUDING SECTION 4*

NOTE: *THIS PRODUCT CAN CONFIGURE EITHER 1~2 WDF 4343RS OR 1~2 WDF 4343RWI*
NOTE: *THIS PRODUCT CAN CONFIGURE EITHER 1~2 ION CHAMBERS OR NOT*
NOTE: *THIS PRODUCT CAN CONFIGURE EITHER ACCUDAP-123 FROM WANDONG OR 120-131 MICRO FROM IBA OR NOT*

WE, *BEIJING WANDONG MEDICAL TECHNOLOGY CO.,LTD.*, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DOC.

STANDARDS APPLIED: *SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.*

NOTIFIED BODY:	*TÜV SÜD PRODUCT SERVICE GMBH* *RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY*
IDENTIFICATION NUMBER	CE *0123*
(EC) CERTIFICATE(S):	G1 043895 0011 REV.02
EC REP EUROPEAN REPRESENTATIVE:	*SHANGHAI INTERNATIONAL HOLDING CORP.GMBH(EUROPE)* *EIFFESTRASSE 80, 20537HAMBURG,GERMANY*

START OF CE-MARKING: *2021-01-12*

PLACE, DATE OF DECLARATION: *CITY, DATE* 2021.1.12

SIGNATURE: _____

NAME:
POSITION: (RESPONSIBLE SENIOR EXECUTIVE OF MANUFACTURER)

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

ATTACHED LIST:

IEC 60601-1:2005+A1:2012	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-3:2008+A1:2013	Medical electrical equipment -- Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-8:2006+A1:2012	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
IEC 60601-2-28:2017	Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-54:2009 +A1:2015+A2:2018	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
ISO 14155:2011	Clinical investigation of medical devices for human subjects – Good clinical practice
EN ISO 14971:2012	Medical devices- Application of risk management to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 1041: 2008+A1:2013	Information supplied by the manufacturer with medical devices
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices
IEC 62304:2006+A1:2015	Medical device software - Software life-cycle processes
ISO 15223-1: 2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirement
ISO 780: 2015	Packaging-Distribution packaging-Graphical symbols for handling and storage of packages
IEC TR 60788:2004	Medical electrical equipment - Glossary of defined terms
IEC TR 60878: 2015	Graphical symbols for electrical equipment in medical practice
IEC 62563-1:2009+A1:2016	Medical electrical equipment – Medical image display systems – Part 1: Evaluation methods