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. **215** din **28.09.2023**

"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 I, Rule 13 annex IX of MDR**:

1. Colposcop binocular cu sistem video de rezolutie inaltă, denumire comercială – **KERNEL MEDICAL (colposcope System)**, model – **KN-2200B**, producător – **Xuzhou KERNEL MEDICAL EQUIPMENT CO., LTD**, țara de origine **- China**;

Se anexează următoarele acte:

1. Împuternicirea de la Producator din 04.09.2023;
2. Declaratie de conformitate **Xuzhou KERNEL MEDICAL EQUIPMENT CO., LTD** din 03.12.2021
3. Certificat ISO 13485:2016 No.**04723Q10000357** din 07.07.2023 (valabil pînă la 06.07.2026);
4. Declaraţie pe proprie răspundere.

Data **28.09.2023**

Semnătura Digitally signed by Lungu Ion
Date: 2023.09.29 13:42:45 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 deţin 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. Colposcop binocular cu sistem video de rezolutie inaltă, denumire comercială – **KERNEL MEDICAL (colposcope System)**, model – **KN-2200B**, producător – **Xuzhou KERNEL MEDICAL EQUIPMENT CO., LTD**, țara de origine **- China**;

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia *Semnătura*

_____

Lungu Ion, Administrator
+37379627404, +37369423432 Data 28.09.2023

DECLARATION OF CONFORMITY
TO REGULATION (EU) 2017/745 OF 5 April 2017
CONCERNING MEDICAL DEVICES

Xuzhou Kernel Medical Equipment Co., Ltd.
Kernel Mansion, Economic Development District, Xuzhou City, Jiangsu Province, China.

Medical Device: Colposcope System
Model: KN-2200、KN-2200A、KN-2200Ⅰ、KN-2200B、KN-2200BⅡ、KN-2200Ⅰ(H)
Basic-UDI DI:692879862203E
Classification: class I, rule 13
Conformity assessment Route: Chapters I and III of Annex IX of MDR

WE, XUZHOU KERNEL MEDICAL EQUIPMENT CO., LTD. HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Standards applied: EN ISO14971:2019,EN ISO15223-1:2016, EN1041:2008，EN 60601-1:2006+A1:2013, EN 60601-1-6 :2010, EN60601-1-2:2015 , EN 62304:2006, EN 62366-1:2015.

CE

EC REP
European Representative: Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany
info@caretechion.de

Place, Date of Declaration: City: Xuzhou, Jiangsu/ Date: 2021-12-03

Signature:

Name: Zhao wei

Position: General Manager

科 诺 医 学 仪 器 设 备 有 限 公 司
KERNEL MEDICAL EQUIPMENT CO., LTD.
Add.: Kernel Building, Economic Development District, Xuzhou City, Jiangsu Province, 221004 China
Tel:+86-516-87732209 Fax:+86-516-87732210 www.kernelmedint.com email:sales08@kernelmed.com

Date: Sep.4th,2023

LETTER OF AUTHORIZATION

To Whom it May Concern,

We, **Kernel Medical Equipment Co.ltd**, who are official manufacturer of colposcope system, having headquarters at **_Kernel Building ,Economic Development District ,Xuzhou, Jiangsu province, China**, assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Moldova Republic of, Chisinau, MD-2019, 128, Grenoble str., OF.011

- as authorized representative in the Republic of Moldova in correspondence with the conditions of ***Directive Regulation (EU) n. 2017/745***.
- 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 _Sep.3rd,2024

Signature and stamp

Registration No. 04723Q10357R8M

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

Kernel Medical Equipment Co., Ltd.

Registered address: **Kernel Building, Economic Development District, Xuzhou City, Jiangsu Province, China.**
Manufacturing address: **Kernel Building, Economic Development District, Xuzhou City, Jiangsu Province, China.**

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

The Design, Development, Production and Service of 308nm Excimer System, LED Light Therapy, UV Phototherapy, Colposcope System, Wood's Lamp, Skin and Hair Analysis Device Multi-parameter Patient Monitor, Hair Growth System, Photodynamic Therapy Device.

Date of issue: **July 07, 2023**
Date of expiry: **July 06, 2026**

General manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information are available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

Registration No. 04723Q10000357

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that:

Kernel Medical Equipment Co., Ltd.

Registered address: **Kernel Building, Economic Development District, Xuzhou City, Jiangsu Province, China.**

Manufacturing address: **Kernel Building, Economic Development District, Xuzhou City, Jiangsu Province, China.**

Operates a Quality Management System which complies with the requirements of:

GB/T 42061-2022 idt ISO 13485:2016

For the following scope:

The Design, Development, Production and Service of 308nm Excimer System, LED Light Therapy, UV Phototherapy, Colposcope System, Wood's Lamp, Skin and Hair Analysis Device Multi-parameter Patient Monitor, Hair Growth System, Photodynamic Therapy Device.

Date of issue: **July 07, 2023**

Date of expiry: **July 06, 2026**

General manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

Beijing Hua Guang Certification of Medical Devices Co., Ltd.

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is isilable on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993