

**Către Agenția Medicamentului  
și 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](mailto:info@hms.md), [srl.hms.moldova@gmail.com](mailto:srl.hms.moldova@gmail.com), solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor **clasa de risc I, Rule 13 anex IX of MDR**:

**1. Colposcop binocular cu sistem video de rezoluție înaltă**, 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. Declarație 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. Declarație pe proprie răspundere.

Data **28.09.2023**

Semnătura

**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	

## **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](mailto:info@hms.md), [srl.hms.moldova@gmail.com](mailto:srl.hms.moldova@gmail.com), declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

**1. Colposcop binocular cu sistem video de rezoluție înaltă, 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 și funcția*

\_\_\_\_\_

*Lungu Ion, Administrator*

+37379627404, +37369423432

*Semnătura*

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-2200 I 、KN-2200B、KN-2200B II、KN-2200 I (H)

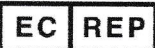
Basic-UDI DI:692879862203E

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.



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

Date: Sep.4<sup>th</sup>,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.3<sup>rd</sup>,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:

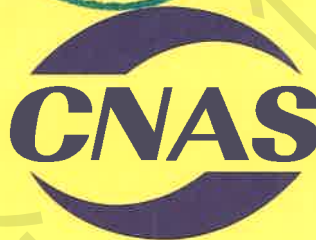
**The Design, Development, Production and Service of 308nm Excimer System, LED Light Therapy, UV Phototherapy, Colposcope System, Wood's Lamp, Skin and Hair Analysis Device Multi-parameter Patient Monitor, Hair Growth System, Photodynamic Therapy Device.**

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

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

General manager:

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



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: 5<sup>th</sup> 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**

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General manager:

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

