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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. 58 din 16.08.2024

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. DISPOZITIV PENTRU LASERTERAPIE, denumirea comercială – Fisioline, model – **LUMIX C.P.S. (LCPS5),** producător – **FISIOLINE S.R.L.**, ţara de origine – Italia, etc;

...

2. DISPOZITIV PENTRU LASERTERAPIE, denumirea comercială – Fisioline, model – **LUMIX PLUS (LPLUS13)** producător – **FISIOLINE S.R.L.**, ţara de origine – Italia, etc;

...

3. DISPOZITIV PENTRU LASERTERAPIE, denumirea comercială – Fisioline, model – **LUMIX ULTRA (LULTRA1901)** producător – **FISIOLINE S.R.L.**, ţara de origine – Italia, etc.;

...

4. DISPOZITIV PENTRU LASERTERAPIE, denumirea comercială – Fisioline, model – **LUMIX Q (LUMIXQ01)** producător – **FISIOLINE S.R.L.**, ţara de origine – Italia, etc.

5. Lista se anexeaza (conf. Listei din formularul Excell);

Se anexează următoarele acte:

1. EC Certificat No. 785/MDD din 20.04.2021;
2. EC Declaraţie de conformitate (Therapeutic laser equipment) din 05.06.2024;
3. Manufacturers Declaration;
4. NB Confirmation Letter;
5. Contract no. 1001C00701228C din 08/06/2023;
6. Document de reprezentanta autorizata;
7. Certificat ISO 13485:2016;
8. Lista dispozitivelor (formularul Excell).

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

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 762119
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	N 8919 din 20.08.2024
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	Valentina Balabaev, şef secţie
Semnătura persoanei responsabile	

AGENŢIA MEDICAMENTULUI ŞI DISPOZITIVELOR MEDICALE MD-2028, mun. Chişinău, str. Korolenko, 2/1 GHIŞEUL UNIC 20 08 2024 Nr.

FISIOLINE S.R.L.
Sede legale:
Borgata Molino, 29 - 12060 VERDUNO (CN) - ITALY
Tel. +39 0172.470432 - +39 0172.470433
https://www.fisioline.com - E-mail: fisioline@fisioline.com
Cod. Fisc./P. IVA/Registro Imprese Cuneo: 01825480047
Codice INTRASTAT: IT 01825480047
Capitale sociale € 50.000,00 interamente versato
N° ISCRIZIONE REGISTRO PRODUTTORI AEE IT08020000001690

DECLARATION OF CONFORMITY

Fisioline S.R.L., seat in Verduno (CN) – Italy – Borgata Molino n.29, legally represented by Mr. Battagliotti Ugo, company administrator, hereby declares that the electromedical equipment of which it is the manufacturer, namely:

Therapeutic laser equipment

- Brand: Fisioline
- Model (REF):

o LUMIX C.P.S. (LCPS5, LCPS6, LCPS12, LCPS17, LCPS29, LCPS31, LCPS701, LCPS702, LCPS901, LCPS902, LCPS1501, LCPS1502)
o LUMIX PLUS (LPLUS13, LPLUS30, LPLUS1001, LPLUS1002, LPLUS1601, LPLUS1602, LPLUS13HP, LPLUS30HP, LPLUS1002HP, LPLUS1001HP, LPLUS1601HP, LPLUS1602HP)
o LUMIX ULTRA (LULTRA1901, LULTRA1902, LULTRA21, LULTRA33, LULTRA35, LULTRA1901HP, LULTRA1902HP, LULTRA21HP, LULTRA33HP, LULTRA35HP)
o LUMIX Q (LUMIXQ01)

Medical devices classification according to the classification rules of the annexe IX (rule 9), mentioned in article 9 of the Directive 93/42/EEC modified by the Directive 2007/47/EC:
o LUMIX C.P.S., LUMIX ULTRA, LUMIX PLUS, LUMIX Q: **class IIb**

Electromedical Classification according to IEC60601-1:
o LUMIX ULTRA, LUMIX PLUS, LUMIX Q: **class I type B**
o LUMIX C.P.S.: **class I type BF**
Laser sources classification according to IEC60825-1:
o LUMIX C.P.S., LUMIX ULTRA, LUMIX PLUS, LUMIX Q: **class 4**

The equipment complies with the essential requirements demanded by the 93/42/EEC Directive concerning medical devices, modified by the 2007/47/EC Directive. The equipment is provided with mark CE 0051 in compliance with this Directives:

- Notified Body: IMQ
- Certificate: 785/MDD
- Certification procedure: Annex II

The general safety norms for electromedical devices IEC 60601-1 are all taken into account together with the particular standard IEC 60601-2-22 and collateral standard IEC 60601-1-6.
The equipment is also manufactured workmanlike for what hygiene, health and safety at work are concerned and in compliance with the current environment protection standards.

The manufacturer preserves and keeps available for the Notified Body and the Competent Authority the whole documentation regarding the product for a minimum period of 5 years starting from the manufacturing date.

The manufacturer, after the introduction of the medical device in the market, has notified to the Competent Authority the application of the post-sale surveillance procedures as required by the Directive (EU) 2017/745 related to the medical devices (MDR).
In witness thereof,

FISIOLINE S.R.L.
THE ADMINISTRATOR
BATTAGLIOTTI UGO

Mod. 57

VERDUNO, 05/06/2024

EC CERTIFICATE

Certificate No 785/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

FISIOLINE SRL

12060 VERDUNO (CN) - BORGATA MOLINO 29 (ITA) - Italy

manages in the factory of:

12060 VERDUNO (CN) - BORGATA MOLINO 29 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Nerve and muscle stimulators

Therapeutic laser equipment

Ultrasound therapy equipment

Pressure therapy equipment

Radartherapy equipment

Equipment for diathermic therapy

Surgical laser

Magnetotherapy equipment

series and type refs in the Annex

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10AE00166; 10AF00006; 10AF00080; 10AG00002; 10AG00215; 10AH00239; 10AI00193; 10AJ00035; 10AJ00017; 10AJ00081; 10EK00056; COMEDCONMHDM110020008-01; COMEDCONMHDM110045943-01; 10EM00020; 10EO00066; DM15A0429779-01; DM15S0487963-01; DM15A0548810-01; DM16-0003004; DM17-0010067-01; DM19-0035008-01; DM19-0041272-01; DM20-0052562-01; DM20-0056063-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2004-09-16
Updated:	2021-04-20
Substitution Date:	2020-07-16
Expiry Date:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 785/MDD

Annex

Nerve and muscle stimulators

Type ref. WINNER; MODULO; MODULO PLUS

Therapeutic laser equipment

Type ref. LUMIX 2; LUMIX 250; LUMIX 100; LUMIX EPIL MED; LUMIX ULTRA; LUMIX PLUS; LUMIX CPS; LUMIX CW; LUMIX Q

Ultrasound therapy equipment

Type ref. FISIOSONIC; FISIOSONIC PLUS; FISIOSONIC BEAUTY MED HF; FISIOSONIC TOTAL FREQUENCY; FISIOSONIC BEAUTY MED LF; FISIOSONIC BEAUTY FACE EP MED; FISIOSONIC MOBILE; O.P.A.F. THERAPY

Pressure therapy equipment

Type ref. LINFOPRESS STUDIO; LINFOPRESS EASY; LINFOPRESS MASTER; LINFOPRESS BEAUTY MED; LINFOPRESS ALIZE' MED; LINFOPRESS ALIZE' MED ST

Radartherapy equipment

Type ref. FISIOWAVE

Equipment for diathermic therapy

Type ref. FISIOLINE RADIANT 200; FISIOLINE RADIANT 300; FISIOLINE RADIANT 400; FISIOLINE RADIANT MOBILE

Surgical laser

Type ref. LUMIX SURGERY; LUMIX SURGERY DENTAL; LUMIX SURGERY DUAL; LUMIX Q PLATFORM

Magnetotherapy equipment

Type ref. FISIOFIELD MAXI; FISIOFIELD MIDDLE; FISIOFIELD MINI

.

Trade mark FISIOLINE

Date:	2004-09-16
Updated:	2021-04-20
Substitution Date:	2020-07-16
Expiry Date:	2024-05-26

IMQ

DocuSign

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	FISIOLINE SRL
Manufacturer address and contact details	Borgata Molino 29, Verduno (CN) - Italy
Single Registration Number (SRN) (if available)	IT-MF-000027924

Authorised Representative name (if applicable)	
Authorised Representative address and contact details	
Single Registration Number (SRN) (if available)	

Notified body name (if applicable)	IMQ S.p.A. □ See attached schedule
Notified body number (if applicable)	0051 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	785/MDD □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-31-12 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule 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,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

X Expired/expires *after* 20 March 2023:

Choose one applicable statement:

X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices (NOT APPLICABLE)**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

X A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Signed for and on behalf of the manufacturer:

Full Company Name FISIOLINE SRL

Location & Date Verduno, 18/04/2024

Signature, Print Name, Title Mr. Ugo Battagliotti

Contact Details (at least email) fisioline@fisioline.com

CISQ is a member of

IQNET

The International Certification Network

www.iqnet-certification.com

CERTIFICATO N.
CERTIFICATE N. **9124.FIS2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

FISIOLINE SRL

BORGATA MOLINO 29 - 12060 VERDUNO (CN) Italy

UNITA' OPERATIVE / *OPERATIVE UNITS*

BORGATA MOLINO 29 - 12060 VERDUNO (CN) Italy

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione ed assistenza di apparecchiature elettromedicali per fisioterapia, per trattamenti di medicina estetica e per laserterapia in applicazioni dentali
Design, production and maintenance of physiotherapic medical equipment, aesthetic medicine equipment and laser therapy for dental applications

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	17-03-1998	10-03-2024	13-04-2027

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

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