Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Digitally signed by Grecu Mihnea Ioan
Date: 2023.11.12 14:33:24 EET
Reason: MoldSign Signature
Location: Moldova

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 06.11.2023

Solicitantul **X-Lab Solutions,** cu sediul **Chisinau str. Negresteni 9, of.11** (adresa), tel./fax: 069036890, e-mai seap@xlab.ro, 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:

- **Procesator de tesut cu vacuum, model: Pro 200.**

Se anexează următoarele acte:

-Lista DM (model);
-Declaratia pe propria raspundere;
-Declaratii de Conformitate;
-Scrisoarea de autorizare (reprezentant autorizat);
-ISO producator;
-Manual (electronic).

Data: 06.11.2023 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	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

Lista Dispozitive Medicale conform Regulament (UE) 746/2017

Nr. Registrul de Stat al Dispozitivelor Medicale	Numărul de catalog (referință) *	Denumire	Modelul	Tip dispozitiv	Cod GMDN
-	-	PROCESATOR DE TESUT CU VACUUM	PRO 200	dispozitiv medical	-

Data: 06.11.2023

X-Lab Solutions
Administrator Executiv
Grecu Mihnea Ioan
Semnătura _____

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului şi Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **X-Lab Solutions Moldova**, cu sediul **Chisinau, str. Negresteni 9 of.11**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

- ✓ **Procesator de tesut cu vacuum, model: Pro 200.**

Sunt autentice şi corespund realităţii.

Numele, prenumele şi funcţia:
Administrator Executiv - Grecu Mihnea Ioan

Semnătura .....

Data 06.11.2023

Histo-Line Laboratories

TO WHOM IT MAY CONCERN

September 08th, 2023

Letter of Authorization

We, Histo-Line Laboratories Srl, located in Via Giuseppe di Vittorio, 30, 20048 Pantigliate MI, Italy, manufacturer of following medical devices:

- **VACUUM TISSUE PROCESSOR, product type: PRO-200.**

hereby confirm that the company **X-Lab Solutions** headquarters in Chisinau, Negresteni street no. 9, ap. of. 11, phone/fax number: 069036890, **is appointed as our representative authorized to register, notify, renew or modify the registration of our medical devices, accessories and consumables related, on the territory of the Republic of Moldova.**

This letter of authorization is valid until 31.12.2023.

Kind regards,

Histo-Line Laboratories Srl
Name, surname: Fabrizio Illuminati
Title: Managing Director

REPUBLICA MOLDOVA, mun. CHISINAU
X-LAB SOLUTIONS S.R.L.
IDNO 1014600019950

CERTIFICATE

Reg. Number	14622 A - A	Valid From	2022-02-18
First issue date	2019-02-20	Last change date	2022-02-18
Valid Until	2025-02-19	IAF Sector	29, 19

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

HISTO-LINE LABORATORIES S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing, aftermarket support of diagnosis equipment for research and diagnostic laboratories.
Distribution and aftermarket support of diagnostic equipment, in-vitro diagnostic devices, reagents and consumables for research and diagnostic laboratories

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia
(BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

HISTO-LINE LABORATORIES S.r.l.
Registered Headquarters
- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia

Certified Sites
- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) Italia

REPUBLICA MOLDOVA, mun. CHIȘINĂU · X-LAB SOLUTIONS S.R.L. · IDNO 1014600019850 · SOCIETATEA CU RĂSPUNDERE LIMITATĂ

CERMET IAF ACCREDIA

CERTIFICATE

Reg. Number	14622 - M	Valid From	2022-02-18
First issue date	2016-03-10	Last change date	2022-02-18
Valid until	2025-03-09		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

HISTO-LINE LABORATORIES S.r.l.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Design, manufacturing, aftermarket support of diagnosis equipment for research and diagnostic laboratories.
Distribution and aftermarket support of diagnostic equipment, in-vitro diagnostic devices, reagents and consumables for research and diagnostic laboratories

Chief Operating Officer
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

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HISTO-LINE LABORATORIES S.r.l.
Registered Headquarters
- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) - Italia
Certified Sites
- Viale Giuseppe di Vittorio, 30 20090 Pantigliate (MI) - Italia

Histo-Line Laboratories

DICHIARAZIONE DI CONFORMITÀ
CE

EC Declaration of Conformity

FABBRICANTE
Manufacturer

HISTO-LINE LABORATORIES S.R.L.
VIALE GIUSEPPE DI VITTORIO, 30
20048 PANTIGLIATE (MI) ITALY

SINGLE REGISTRATION NUMBER (SRN) **IT-MF-000029019**

PRODOTTI ***Products***	**Come da lista allegata** ***See attached list***
REGOLA DI CLASSIFICAZIONE ***Classification Rule***	**Classe A, Regola 5 Regolamento UE 2017/746, Allegato 8** ***Class A, Rule 5 EU Regulation 2017/746, Annex 8***

LA DICHIARAZIONE DI CONFORMITÀ È RILASCIATA SOTTO ESCLUSIVA RESPONSABILITÀ DEL FABBRICANTE.
DICHIARIAMO ED ASSICURIAMO SOTTO LA NOSTRA RESPONSABILITÀ CHE I PRODOTTI SOPRAMENZIONATI SONO CONFORMI REGOLAMENTO UE 2017/746 RELATIVO AI DISPOSITIVI MEDICO-DIAGNOSTICI IN VITRO.
DICHIARIAMO INOLTRE:

- **I PRODOTTI SOPRAMENZIONATI SONO CONFORMI AI REQUISITI ESSENZIALI ELENCATI IN ALLEGATO I DEL REGOLAMENTO UE 2017/746.**
- **I DISPOSITIVI SONO PROGETTATI, PRODOTTI ED IMMESSI IN COMMERCIO IN ACCORDO AL SISTEMA QUALITÀ AZIENDALE CERTIFICATO ISO 13485,**
- **L'AZIENDA HA ISTITUITO E TIENE IN ATTO PROCEDURE PER GARANTIRE LA SORVEGLIANZA POST VENDITA COSÌ COME RICHIESTO DALLE AUTORITÀ COMPETENTI EUROPEE,**
- **TUTTI I DOCUMENTI DI SUPPORTO SONO CONSERVATI PRESSO GLI UFFICI DEL FABBRICANTE.**
- **I DISPOSITIVE SONO CONFORMI AI SEGUENTI STANDARD ARMONIZZATI: ISO 13485 - ISO 15223- ISO 14971**

EU declaration of conformity is issued under the sole responsibility of the manufacturer.
We declare and assure under our responsibility that the above mentioned products complies with the EU Regulation 2017/746 on In vitro diagnostic medical devices.
Furthermore, we declare too:

- ***the products are complies with the essential requirements listed in the Annex I of the EU Regulation 2017/746***
- ***the devices is designed, manufactured and placed on the market according to the Certified Quality System ISO 13485,***
- ***the company have instituted and keep up to date an adequate procedure to guarantee the market surveillance as requested by competent authorities,***
- ***all supporting documentation is retained under the premises of the manufac***
- ***the devices are in accordance this list of harmonized standards: ISO 134 ISO 15 ISO 14971***

LUOGO, DATA DI EMISSIONE **PANTIGLIATE, 20/03/2023**
place, date of issue

REPUBLICA MOLDOVA, mun. CHIȘINĂU
X-LAB SOLUTIONS S.R.L.
IDNO 1014600019950
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

LEGALE RAPPRESENTANTE
LEGAL REPRESENTATIVE

Histo-Line Laboratories

DICHIARAZIONE DI CONFORMITÀ

CE

EC Declaration of Conformity

Attachment - Products List

Product group: SAMPLES TREATMENT INSTRUMENTS

Basic UDI: 803403436HLSTR7S

Product code	Product name	Intended use
ATS 2010	Automatic Slide Tissue Stainer	Used for slide automatic staining
ATS 200	Automatic Slide Tissue Stainer	Used for slide automatic staining
TEC 2900-1	Main Console	Used for paraffin dispensing
TEC 2900-2	Cryo Console	Used for paraffin cooling
TEC 2900-3	Thermal Console	Used for samples heating
TEC 2900-4	Thermal Console double floor	Used for samples heating
SP 100	Cytological Centrifuge	Used for tissue treatment
MR 2258	Manual rotary microtomes	Used for cutting. trimming and counting of biological samples
MR 3000	Manual rotary microtomes	Used for cutting. trimming and counting of biological samples
ATP 1000	Automatic Tissue Processor	Used for tissue processing
PRO 200	Vacuum Tissue Processor	Used for tissue processing
PRO 300	Vacuum Tissue Processor	Used for tissue processing
STP 250	Spin Tissue Processor	Used for tissue processing
STP 250V	Spin Vacuum Tissue Processor	Used for tissue processing
TEC 2500	Water Bath Slide Dryer All In One	Used for slide drying
WB 2800	Water Bath	Used for flattening tissue slices
WB 2900	Tissue Floating Bath	Used for flattening and drying tissue slices
SD 2800	Slide Dryer	Used for slide drying
TEC 2000	Paraffin Dispenser	Used for paraffin dispensing
MR 3000	Manual rotary microtomes	Used for cutting. trimming and counting of biological samples

Histo-Line Laboratories

DICHIARAZIONE DI CONFORMITÀ
CE

EC Declaration of Conformity

Product code	Product name	Intended use
MRS 3500	Semiautomatic Microtome	Used for cutting, trimming and counting of biological samples
ARM 3600	Fully Motorized Rotary Microtome	Used for automatic cutting trimming and counting of biological samples.
ARM 3700	Fully Motorized Rotary Microtome	Used for automatic cutting trimming and counting of biological samples.
ARM 3750	Fully Motorized Rotary Microtome	Used for automatic cutting trimming and counting of biological samples.
MC 3000	Microtome Cryostat	Used for cutting, trimming and counting of biological samples (frozen).
MC 4000	Microtome Cryostat	Used for cutting, trimming and counting of biological samples (frozen).
MC 5000	Microtome Cryostat	Used for cutting, trimming and counting of biological samples (frozen).
MC 5050	Microtome Cryostat	Used for cutting, trimming and counting of biological samples (frozen).
STP 250-DUO	Spin Vacuum Tissue Processor – Double basket	Used for tissue processing