

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 DISPOSITIVI SONO CONFORMI AI SEGUENTI STANDARD ARMONIZZATI: ISO 13485 - ISO 15223- ISO 14971 - CEI EN 61010-CEI EN 61326

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 manufacturer,*
- *the devices are in accordance this list of harmonized standards: ISO 13485 - ISO 15223- ISO 14971 - CEI EN 61010-CEI EN 61326*

LUOGO, DATA DI EMISSIONE
place, date of issue

PANTIGLIATE, 20/03/2023

LEGALE RAPPRESENTANTE
LEGAL REPRESENTATIVE

Histo-Line Laboratories S.r.l.


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

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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

Histo-Line Laboratories S.p.A.
[Handwritten Signature]