



# 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

*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 insituted 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*

LUOGO, DATA DI EMISSIONE  
*place, date of issue*

PANTIGLIATE, 13/07/2023

LEGALE RAPPRESENTANTE  
*LEGAL REPRESENTATIVE*

**Attachment - Products List**

**Product group:** STAINING REAGENTS

**Basic UDI:** 803403436HLSTA6Q

Product code	Product name	Intended use
013408-1-100	Tissue marking dyes green, 100 mL	Marking system
013408-1-250	Tissue marking dyes green, 250 mL	Marking system
013408-2-100	Tissue marking dyes yellow, 100 mL	Marking system
013408-3-100	Tissue marking dyes black, 100 mL	Marking system
013408-3-250	Tissue marking dyes black, 250 mL	Marking system
013408-4-100	Tissue marking dyes red, 100 mL	Marking system
013408-5-100	Tissue marking dyes blue, 100 mL	Marking system
013408-5-250	Tissue marking dyes blue, 250 mL	Marking system
013408-6-100	Tissue marking dyes orange, 100 mL	Marking system
013408-7-100	Tissue marking dyes lilac, 100 mL	Marking system
013408-SET-7	Tissue marking dyes kit, 7x50 mL	Marking system
01HEMH1000	Hematoxylin Harris, 1000 mL	Nuclear stain
01HEMH2500	Hematoxylin Harris, 2500 mL	Nuclear stain
01HEMM1000	Hematoxylin Mayer, 1000 mL	Nuclear stain
01HEMM500	Hematoxylin Mayer, 500 mL	Nuclear stain
01HEMCA500	Hematoxylin Carazzi, 500 mL	Nuclear stain
01EOY052500	Eosin Y 0,5% aqueous solutions, 2500 mL	Cytoplasmic stains
01EOY101000	Eosin Y 1% aqueous solutions, 1000 ml	Cytoplasmic stains
01EOYA101000	Eosin Y 1% alcoholic solutions, 1000 mL	Cytoplasmic stains
01EOYA051000	Eosin Y 0,5 % alcoholic solutions, 1000 mL	Cytoplasmic stains
01EOYKP2500	Eosin Contrast Plus, 2500 mL	Cytoplasmic stains

Product code	Product name	Intended use
01HEMHP500	Hematoxylin Harris Pap 1A - Papanicolau, 500 mL	Nuclear stain
01HEMHP1000	Hematoxylin Harris Pap 1A - Papanicolau, 1000 mL	Nuclear stain
01HEMHP1B2500	Hematoxylin Harris Pap 1B - Papanicolau, 2500 mL	Nuclear stain
01HEMHP2500	Hematoxylin Harris Pap 1A - Papanicolau, 2500 mL	Nuclear stain
01OG6500	OG-6 Stain Solution - Papanicolaou, 500 mL	Cytoplasmic staining reagents
01OG61000	OG-6 Stain Solution - Papanicolaou, 1000 mL	Cytoplasmic staining reagents
01OG62500	OG-6 Stain Solution - Papanicolaou, 2500 mL	Cytoplasmic staining reagents
01EA50500	EA-50 Stain Solution - Papanicolaou Pap3B, 500 mL	Cytoplasmic staining reagents
01EA501000	EA-50 Stain Solution - Papanicolaou Pap3B, 1000 mL	Cytoplasmic staining reagents
01EA502500	EA-50 Stain Solution - Papanicolaou Pap3B, 2500 mL	Cytoplasmic staining reagents
01AB100T	Alcian blu P.A.S. - Kit, 100 tests	Special stains for histology and cytology
01AB10100T	Alcian blue pH 1 – kit, 100 tests	Special stains for histology and cytology
01AB25100T	Alcian blu pH 2,5 - kit,100 tests	Special stains for histology and cytology
01AZT100T	Azan Trichrome Kit,100 tests	Special stains for histology and cytology
01BGRH100T	BioGram Histo kit, 100 tests	Special stains for histology and cytology
01KOL100T	Colloidal Iron Kit, 100 tests	Special stains for histology and cytology
01CR100T	Congo Red Highman - kit, 100 tests	Special stains for histology and cytology
01CRP100T	Congo Red Puchtler – kit, 100 tests	Special stains for histology and cytology

Product code	Product name	Intended use
01WVGB100T	Elastica-Van Gieson – kit, 100 tests	Special stains for histology and cytology
01FVG100T	Fouchet-Van Gieson - kit, 100 tests	Special stains for histology and cytology
01GMHP100T	Giemsa HP – kit, 100 tests	Special stains for histology and cytology
01GT100T	Gomori trichrome - kit, 100 tests	Special stains for histology and cytology
01GRC100T	Grocott - kit, 100 tests	Special stains for histology and cytology
01HPTA100T	P.T.A. hematoxylin - kit, 100 tests	Special stains for histology and cytology
01HPTA100	P.T.A. hematoxylin, 100 ml	Special stains for histology and cytology
01HP100T	Emognost Perls - kit, 100 tests	Special stains for histology and cytology
01LFB100T	Luxol Fast Blue - kit, 100 tests	Special stains for histology and cytology
01MF100T	Masson Fontana - kit, 100 tests	Special stains for histology and cytology
01MGT100T	Masson Trichrome Goldner – kit, 100 tests	Special stains for histology and cytology
01MST100T	Masson Trichrome – kit, 100 tests	Special stains for histology and cytology
01MUC100T	Mucicarmine - kit, 100 tests	Special stains for histology and cytology
01ORC100T	Orcein - kit, 100 tests	Special stains for histology and cytology
01PAS5100T	P.A.S. - kit, 100 tests	Special stains for histology and cytology
01PASM100T	P.A.S.M. /Jones - kit, 100 tests	Special stains for histology and cytology
01RE100T	Reticulin - kit, 100 tests	Special stains for histology and cytology
01RET100T	Reticulin contrast - kit, 100 tests	Special stains for histology and cytology

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PRODOTTI  
*Products*

Come da lista allegata  
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REGOLA DI CLASSIFICAZIONE  
*Classification Rule*

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LUOGO, DATA DI EMISSIONE  
*place, date of issue*

PANTIGLIATE, 11/04/2023

LEGALE RAPPRESENTANTE  
*LEGAL REPRESENTATIVE*



Attachment - Products List

Product group: PROCESSING AND AUXILIARY REAGENTS FOR  
HISTOLOGY/CYTOLOGY

Basic UDI: 803403436HLPROC95

Product code	Product name	Intended use
R0055-2.5	Diaphane, 4x2.5 L	Clarifying solutions
R0055-20	Diaphane, 4x5 L	Clarifying solutions
R0060	Histo-Decal, 6x1 L	Decalcifying solutions
R050CITRO	Citro HistoClear, 4x5 L	Clarifying solutions
R0020	Ice Spray, 12x200 mL	Freezing solutions

Histo-Line Laboratories S.r.l.  


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20048 PANTIGLIATE (MI) ITALY

SINGLE REGISTRATION NUMBER (SRN) IT-MF-000029019

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LUOGO, DATA DI EMISSIONE  
*place, date of issue*

PANTIGLIATE, 23/01/2023

LEGALE RAPPRESENTANTE  
*LEGAL REPRESENTATIVE*

  
Histo-Line Laboratories S.R.L.

**DICHIARAZIONE DI CONFORMITÀ**  
**CE**  
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**Attachment - Products List**

**Product group:** EMBEDDING MEDIA

**Basic UDI:** 803403436HLEMB3X

<b>Product code</b>	<b>Product name</b>	<b>Intended use</b>
01CF100	Gel CryoFix, 100 mL	Infiltration, embedding and demolding media
01TS1000	Tissue soft, 1 L	Infiltration, embedding and demolding media
R0040 PLUS	LAB-O-WAX Plus, 6x2 Kg	Infiltration, embedding and demolding media
22-126	Cryochem, 10 x 250 mL	Infiltration, embedding and demolding media

Histo-Line Laboratories S.r.l.  






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PANTIGLIATE, 23/01/2023

LEGALE RAPPRESENTANTE  
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**Attachment - Products List**

**Product group:** MOUNTING MEDIA

**Basic UDI:** 803403436HLMOU6K

<b>Product code</b>	<b>Product name</b>	<b>Intended use</b>
01BM100	BioMount DPX, 100 mL	Covering/ mounting media
01BM500	BioMount DPX, 500 mL	Covering/ mounting media
01BML500	HistoMount DPX LOW, 500 mL	Covering/ mounting media
01BMN500	HistoMount New, 500 mL	Covering/ mounting media
01BMNL500	HistoMount New Low, 500 mL	Covering/ mounting media
01BMT500	BioMount, 500 mL	Covering/ mounting media
01BMA100	HistoMount Aqua, 100 mL	Covering/ mounting media
01BMA30	HistoMount Aqua, 30 mL	Covering/ mounting media
01BMT1000	BioMount, 1000 mL	Covering/ mounting media
R0030	O.C.T. Compound, 12x130 ml	Covering/ mounting media



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PANTIGLIATE, 23/01/2023

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Histo-Line Laboratories S.R.L.  


Attachment - Products List

Product group: PROCESSING AND AUXILIARY REAGENTS FOR  
HISTOLOGY/CYTOLOGY

Basic UDI: 803403436HLPROC95

Product code	Product name	Intended use
01OF11000	Osteofast 1, 6 FL x 1L	Decalcifying solutions
01OS1000	Osteosens, 1 L	Decalcifying solutions
01H705000	Histanol 70, 5000 mL	Dehydrating and rehydrating agents
01HG5000	Histanol G - Glycerol, 5000 mL	Dehydrating and rehydrating agents
01HM1000	Histanol M - Metanolo, 1000 mL	Dehydrating and rehydrating agents
01HM5000	Histanol M - Metanolo, 5000 mL	Dehydrating and rehydrating agents
01H1005000	Histanol 100, 5000 mL	Dehydrating and rehydrating agents
01IUA100	Immersion oil type A, 100 mL	Immersion media
01KA1000	Acido alcohol, 1000 ml	Differentiation and bluing reagents
3410	Xilene	Histology and cytology processing
R0055-2.5	Diaphane, 4x2.5 L	Clarifying solutions
R0055-20	Diaphane, 4x5 L	Clarifying solutions
R0060	Histo-Decal, 6x1 L	Decalcifying solutions
R050CITRO	Citro Histo-clear, 4x5 L	Dehydrating and rehydrating agents

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