

CERTIFICATE

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

Milestone S.r.l.

Via Fatebenefratelli, 1/5

IT – 24010 Sorisole (BG)

Corso Europa Unità, 6

IT – 24030 Valbrembo (BG)

has established and applies a quality management system
for the following scope:

Design of laboratory equipment and reagents for medical applications. Manufacture, marketing under its own brand and maintenance of laboratory equipment for medical applications. Manufacturing management of reagents for medical applications.

Through an Audit, Report No. 28119465 001, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2016

Please refer to the Quality Manual for the details about the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 0101102**.

This Certificate is valid from 2020-05-25 to 2023-05-27.

The reference date for all the next audits is (day-month): 16-05.

Milan, ~~2020~~-05-25. First Certification: 2011-05-28



The certification responsible: Massimiliano Testi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20010 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC or 98/79/EC have been fulfilled.



SGQ N° 083A SGA N° 052D

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC

Signatory of EA, IAF and ILAC Mutual Recognition Agreement



Management System
EN ISO
13485:2016

www.tuv.com
ID 9105063394



www.tuvitalia.com

 **TÜVRheinland®**

MILESTONE



HELPING
PATIENTS

DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

MILESTONE S.R.L.

(nome del fabbricante) (manufacturer's name) ()

Via Fatebenefratelli, 1/5 – 24010 SORISOLE (BG) – ITALY

(indirizzo) (address) ()

Dichiariamo sotto la nostra esclusiva responsabilità che il prodotto / sistema
Declare under our sole responsibility that the product / system

HISTODREAM M

(denominazione commerciale) (trade name) ()

Al quale questa dichiarazione fa riferimento, è conforme con le seguenti norme
To which this declaration relates is in conformity with the following standards

IEC 61010-2-101:2015, IEC 61010-1:2010/AMD2016

IEC 61326-2-6:2012 and IEC 61326-1:2012

(titolo e/o numero e data) (title and/or number and date) ()

Secondo le prescrizioni delle Direttive:
Following the provisions of Directive(s):

2014/35/EC, 2011/65/EC and 2015/863/EC

(titolo e/o numero della direttiva) (title and/or number of directive) ()

Secondo le prescrizioni del Regolamento:
According to the regulations of the Regulations:

2017/746

(titolo e/o numero della regolamentazione) (title and/or number of directive) ()

Classe di rischio in accordo all'allegato VIII:
Risk class in accordance with Annex VIII:

Class A

(classe) (class) ()

- Autodichiarazione: La presente dichiarazione di conformità è redatta secondo l'Art. 17 del Regolamento 2017/746, applicando la procedura di valutazione della conformità secondo quanto indicato dall'Art. 48, comma 10.
- Self-declaration: This Declaration of Conformity is drawn up in accordance with article 17 of Regulation 2017/746, applying the conformity assessment procedure as set out in article 48, paragraph 10

BASIC UDI

805247898MICROTOME4H

(UDI di base) (Basic UDI) ()



Refer to annex for references
Soriso, 2022-05-23

VISINONI Francesco
PRESIDENT – MILESTONE s.r.l.



DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY

REF	Dispositivo Device	Alimentazione Power supply voltage	Tipo Type	Vedi note See note
500300	HISTODREAM M	100-240V~ 50/60Hz	D	1,2
500375	DREAMBLADES 35LH		A	1
500376	DREAMBLADES 35LH		A	1
500380	DREAMBLADES 35HH		A	1
500381	DREAMBLADES 35HH		A	1

Legenda / Legend:

Tipo / Type:

- D = Dispositivo / Device
- S = Software / Software
- A = Accessorio / Accessory

Note / Notes :

(1): Conforme al / Comply to: 2017/746,

(2): Conforme alle / Comply to: 2014/35/EC, 2011/65/EC and 2015/863/EC.