

CERTIFICATE

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

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

Milestone S.p.A.

Via Fatebenefratelli, 1/5

IT – 24010 Sorisole (BG)

MILESTONE



HELPING
PATIENTS

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

Design and development, manufacturing and placing into market of laboratory medical equipment.

Design and development, management of manufacturing and placing into market of reagents for medical use.

Trade of reagents and laboratory equipment for medical use.

Installation and service of laboratory equipment for medical use.

Through an Audit proof has been furnished that the
quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

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 2026/05/28 to 2029/05/27.

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

Milan, 2026/05/27. First Certification: 2011/05/28

The certification responsible: Mauro De Angiolini
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives
93/42/EEC, 90/385/EEC, 98/79/EC or
Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



00321

www.tuv.com



Management
System
EN ISO 13485:2016
+AC:2018+A11:2021



www.tuv.com
ID 9105063394

 TÜV Rheinland®

CERTIFICATE

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

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

Milestone S.p.A.

Via Fatebenefratelli, 1/5

IT – 24010 Sorisole (BG)

MILESTONE



HELPING PATIENTS

The scope of certification covers the following:

No. Facility

- /01** Milestone S.p.A.
Via Fatebenefratelli, 1/5 – 24010 Sorisole (BG) IT
Corso Europa Unita, 6 – 24030 Valbrembo (BG) IT
Via Italia, 3 – 24030 Valbrembo (BG) IT
Via Italia, 1/E – 24030 Valbrembo (BG) IT

- /02** Milestone Medical Technologies, Inc.
6475 Technology Ave, suite f
Kalamazoo, Michigan 49009 – USA

Scope

Design and development, manufacturing and placing into market of laboratory medical equipment.
Design and development, management of manufacturing and placing into market of reagents for medical use.

First issue date: 2011/05/28

Trade of reagents and laboratory equipment for medical use.
Installation and service of laboratory equipment for medical use.

First issue date: 2026/05/28

UNI CEI EN ISO 13485:2021

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

This Certificate is valid from 2026/05/28 to 2029/05/27.

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

Milan, 2026/05/27. First Certification: 2011/05/28

The certification responsible: Mauro De Angiolini
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled



00321

www.tuv.com



Management System
EN ISO 13485:2016
+AC:2018+A11:2021



www.tuv.com
ID 9105063394

