







CERTIFICATE OF CONFORMITY

FOR ENVIRONMENTAL MANAGEMENT SYSTEM PER IL SISTEMA DI GESTIONE AMBIENTALE

Certificate No AQS/A/104002023

Name of Company /Rilasciato a: BIOLIFE ITALIANA S.r.l.

P.IVA: IT01149250159

Address/Indirizzo: Viale Monza, 272, Milano 20128 - MI - Italy.

Standard / Norma: **EN-ISO 14001:2015**

Concerning the following for services / È conforme ai requisiti, per il seguente campo applicativo:

Production and marketing of adjuvant media, freeze-dried media for organic crops and haemostatic products.

Produzione e commercializzazione di terreni coadiuvanti, liofili per colture biologiche e prodotti emostatici.

EA Sectors / Settori EA: 01; 13; 29

MQ5CERT



Validity of the Certificate / Validità del certificato:

First Issue/Prima emissione 08/06/2023

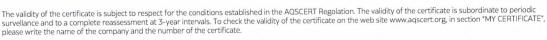
The first maintenance within 08/06/2024

The second maintenance within 08/06/2025

Expiry date/Data di scadenza







mdc medical device certification GmbH

certifies that

Biolife Italiana Srl Viale Monza 272 20128 Milano Italy

for the scope

Design, manufacturing and distribution of in-vitro diagnostic microbiological culture media Distribution of in-vitro diagnostic devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2015)

 Valid from Valid until
 2021-12-20

 Valid until
 2024-08-29

 Registration no.
 D2001500017

 Report no.
 P21-00807-224077

 Stuttgart
 2021-12-20

Head of Certification Body





mdc medical device certification GmbH

certifies that

Biolife Italiana Srl Viale Monza 272 20128 Milano Italy

for the scope

Design, manufacturing and distribution of in-vitro diagnostic microbiological culture media Distribution of in-vitro diagnostic devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices - Quality management systems -Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from 2021-12-20 Valid until 2024-08-29 Registration no. D2001500016 Report no. P21-00807-224075

Stuttgart 2021-12-20

Head of Certification Body





EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Mascia Brunelli S.p.A. Viale Monza 272 20128 Milano Italy

for the scope

Immunochromatographic test for determination of Chlamydia trachomatis antigen
Chlamydia trachomatis controls
Rapid self-testing device for detection of Helicobacter pylori in stool sample

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system meets all requirements according to

Annex IV – excluding Section 4 and 6 of the Council Directive 98/79/EC

of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

The surveillance will be held as specified in Annex IV, Section 5.

 Valid from Valid until
 2022-04-13

 Valid until
 2025-05-26

 Registration no.
 D1016000052

 Report no.
 P21-00806-235224

Stuttgart 2022-04-13

Head of Certification Body













CERTIFICATE OF CONFORMITY

FOR ENVIRONMENTAL MANAGEMENT SYSTEM PER IL SISTEMA DI GESTIONE AMBIENTALE

Certificate No AQS/A/104412023

Name of Company /Rilasciato a: MASCIA BRUNELLI S.p.A.

P.IVA: IT05985320158

Address/Indirizzo: Viale Monza, 272, Milano 20128 - MI - Italy.

Standard / Norma: **EN-ISO 14001:2015**

Concerning the following for services / È conforme ai requisiti, per il seguente campo applicativo:

Production and marketing of adjuvant media, freeze-dried media for organic crops and haemostatic products.

Produzione e commercializzazione di terreni coadiuvanti, liofili per colture biologiche e prodotti emostatici.

EA Sectors / Settori EA: 01; 13; 29

Validity of the Certificate / Validità del certificato:

First Issue/Prima emissione 14/06/2023

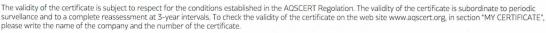
The first maintenance within 14/06/2024

The second maintenance within 14/06/2025

Expiry date/Data di scadenza

13/06/2026







mdc medical device certification GmbH

certifies that

Mascia Brunelli S.p.A. Viale Monza 272 20128 Milano Italy

for the scope

Design, manufacturing and distribution of haemostatic medical devices, in-vitro diagnostic microbiological culture media, platelet aggregation reagents and rapid tests for the detection of infectious diseases

Distribution of medical devices and in-vitro diagnostic devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 9001

Quality management systems – Requirements

(ISO 9001:2015)

 Valid from Valid until
 2021-12-20

 Valid until
 2024-08-29

 Registration no.
 D1016000051

 Report no.
 P21-00806-224070

Stuttgart 2021-12-20

Head of Certification Body





mdc medical device certification GmbH

certifies that

Mascia Brunelli S.p.A. Viale Monza 272 20128 Milano Italy

for the scope

Design, manufacturing and distribution of haemostatic medical devices, in-vitro diagnostic microbiological culture media, platelet aggregation reagents and rapid tests for the detection of infectious diseases.

Distribution of medical devices and in-vitro diagnostic devices.

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

 Valid from Valid until
 2021-12-20

 Valid until
 2024-08-29

 Registration no.
 D1016000050

 Report no.
 P21-00806-224067

Stuttgart 2021-12-20

Head of Certification Body



