CS 008 28.03.22
FULL MEMBER OF EA, IAF. SIGNATORY OF MUTUAL RECOGNITION AGREEMENTS

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.

Digitally signed by Ceaicovschi Tudor
Date: 2024.01.12 14:36:39 EET
Reason: MoldSign Signature
Location: Moldova

EA Sectors / Settori EA: 01; 13; 29

For Certification Body

Validity of the Certificate / Validità del certificato:

First Issue/Prima emissione	The first maintenance within	The second maintenance within	Expiry date/Data di scadenza
08/06/2023	08/06/2024	08/06/2025	07/06/2026

AQSCERT S.r.l. / Jusuf Vrioni Street, Building 1, No 6, 1001, Tirana, Albania / www.aqscert.org info@aqscert.org

Certificate

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	2021-12-20
Valid until	2024-08-29
Registration no.	D2001500017
Report no.	P21-00807-224077
Stuttgart	2021-12-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

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

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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	2022-04-13
Valid until	2025-05-26
Registration no.	D1016000052
Report no.	P21-00806-235224
Stuttgart	2022-04-13

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-247.10.05

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

CS 008 28.03.22
FULL MEMBER OF EA, IAF. SIGNATORY OF MUTUAL RECOGNITION AGREEMENTS

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	The first maintenance within	The second maintenance within	Expiry date/Data di scadenza
14/06/2023	14/06/2024	14/06/2025	13/06/2026

For Certification Body

Eriola Cuni

AQSCERT S.r.l / Jusuf Vrioni Street, Building 1, No 6, 1001, Tirana, Albania / www.aqscert.org info@aqscert.org

Certificate

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	2021-12-20
Valid until	2024-08-29
Registration no.	D1016000051
Report no.	P21-00806-224070
Stuttgart	2021-12-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

mdc medical device certification GmbH
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D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

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	2021-12-20
Valid until	2024-08-29
Registration no.	D1016000050
Report no.	P21-00806-224067
Stuttgart	2021-12-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
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Internet: http://www.mdc-ce.de