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

sterile haemostatic absorbable gelatin and oxidized regenerated cellulose medical devices

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 II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

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

Valid from	2018-08-29
Valid until	2023-08-29
Registration no.	D1016000036
Report no.	P18-00837-123307
Stuttgart	2018-08-29

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-246.10.06

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Mascia Brunelli S.p.A.
Viale Monza 272
Milano 20128
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Your signs, your letter dated	Our signs, our letter dated	Phone number	Date
	DF-PJ	+49 711 253597-288	2023-05-15

Preliminary Confirmation Letter - validity of MDD certificates

To whom it may concern,

mdc medical device certification GmbH (Kriegerstr. 6, 70191 Stuttgart, Germany) has for the manufacturer

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issued the following certificates in accordance with Directive 93/42/EEC:

Certificate registration No.	Certification	Date of issue	Expiry date
D1016000036	93/42/EEC, Annex II, excluding 4	2018-08-29	2023-08-29
D1016000040	93/42/EEC, Annex II, 4	2019-09-20	2024-05-26
D1016000043	93/42/EEC, Annex II, 4	2021-01-26	2023-11-06
D1016000045	93/42/EEC, Annex II, 4	2021-04-09	2023-11-06
D1016000046	93/42/EEC, Annex II, 4	2021-03-26	2024-05-26

These certificates were valid as of 20 March 2023 and have not been withdrawn afterwards. In accordance with the requirements of Art. 120 (2), second subparagraph, first sentence of Regulation (EU) 2017/745 on Medical Devices (MDR), last amended by Regulation (EU) 2023/607 the above mentioned certificates shall remain valid until the date set out in Art 120 (3a) MDR.

This confirmation requires that the manufacturer complies with the requirements laid out in Art. 120 (3c) and (3d) MDR and will undergo further surveillance according to the rules of mdc medical device certification GmbH.

According to the requirements of Art. 120 (3a) MDR, the prerequisite for placing the concerned devices on the market is fulfilled until at least 26 May 2024, unless otherwise specified by the authorities or this letter is replaced by a contrary notification by mdc.

Kind regards,

mdc medical device certification GmbH

i. A. Daniela Franck
(Team Management)

ID: 10727– 002/04.2023
mdc medical device certification GmbH

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General Manager
Chairman of the board
Registered office of the company
USt.IDNr DE812169576

Harald Rentschler
Dirk Palige
Stuttgart
AG Stuttgart HRB 21357

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Viale Monza 272
Milano 20128
Italija

Our signs, our letter dated	Telefono numeris	Data
DF-PJ	+49 711 253597-288	2023-05-15

Preliminarus patvirtinimo laiškas – MDD sertifikatų galiojimas

Tiems, kam tai gali būti aktualu,

mdc medicinos prietaisų sertifikatas GmbH (Kriegerstr. 6, 70191 Stuttgart, Vokietija) turi gamintojui

Mascia Brunelli S.p.A.
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pagal Direktyvą 93/42/EEB išdavė šiuos sertifikatus:

Certificate registration No.	Certification	Date of issue	Expiry date
D1016000036	93/42/EEC, Annex II, excluding 4	2018-08-29	2023-08-29
D1016000040	93/42/EEC, Annex II, 4	2019-09-20	2024-05-26
D1016000043	93/42/EEC, Annex II, 4	2021-01-26	2023-11-06
D1016000045	93/42/EEC, Annex II, 4	2021-04-09	2023-11-06
D1016000046	93/42/EEC, Annex II, 4	2021-03-26	2024-05-26

Šie sertifikatai galiojo 2023 m. kovo 20 d. ir vėliau nebuvo atšaukti. Pagal Reglamento (ES) 2017/745 dėl medicinos prietaisų (MDR) 120 straipsnio 2 dalies antros pastraipos pirmas sakinys su paskutiniais pakeitimais, padarytais Reglamentu (ES) 2023/607, pirmiau minėti sertifikatai galioja iki 120 straipsnyje nustatytos datos. (3a) MDR.

Šis patvirtinimas reikalauja, kad gamintojas laikytųsi 2 str. 120 (3c) ir (3d) MDR ir bus toliau stebimi pagal mdc medicinos prietaisų sertifikavimo taisykles.

Pagal 120 str. (3a) MDR reikalavimus, būtina atitinkamų prietaisų pateikimo į rinką sąlyga yra įvykdyta bent iki 2024 m. gegužės 26 d., nebent institucijos nurodytų kitaip arba šis raštas būtų pakeistas priešingu mdc pranešimu.

Su pagarba,

mdc medicinos prietaisų sertifikavimo GmbH

i. A. Daniela Franck
(Komandos vadovas)

signiert von: Daniela Franck
am: 15.05.2023
mit: digiSeal® by secrypt

Dokumentą elektroniniu parašu pasirašė]
Data: 2025-03-06 10:26:03
Paskirtis: Pirkimo nr. 925806
Vieta: Energetikų g. 8, Kaunas
Kontaktinė informacija: Viešųjų pirkimų specialistė

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