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Certified Quality System
ISO 13485:2016
Cert. n° D1016000055
ISO 9001:2015
Cert. n° D1016000056

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service.

Manufacturer name	Mascia Brunelli S.p.A.
Manufacturer address and contact details	Viale Monza 272, 20128 Milan, Italy +39 02/252091 info@masciabrunelli.it
Single Registration Number (SRN) (if available)	IT-MF-000009572

Notified body name	MDC medical device certification GmbH
Notified body number	0483
Directive Certificate numbers to which this confirmation is made	D1016000036 - 93/42/EEC, Annex II excluding section 4 D1016000045 - 93/42/EEC, Annex II, section 4 D1016000058 - Supplement to D1016000045 certificate
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	D1016000036 - Exp. Date 29 August 2023 D1016000045 - Exp. Date 06 November 2023 D1016000058 - Same Exp. Date of D1015000045 certificate
End date of extended validity/transition period	31 December 2027

We, as the manufacturer, declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached table and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

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Directive Certificates as listed above and in the attached table:

- Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been submitted by us to a notified body on 31 March 2022 (as required no later than 26 May 2024) for the devices listed in the attached table, and signed written agreements is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR on 16 September 2022 (before 26 September 2024).

Quality Management System (QMS)

- A QMS in accordance with Article 10(9) MDR is in place.

Device as listed in the attached schedule

- The device continues to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device does not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name	**Mascia Brunelli S.p.A.**
Location & Date	**Milan, 05 September 2024**
Signature, Print Name, Title	**Beatrice Brunelli, CEO**
Contact Details (at least email)	**regulatory@masciabrunelli.it**

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / ttransition period**
Ref. 60036568 Gelatamp Forte 10x10x4 mm	D1016000036	29 August 2023	0483 - MDC medical device certification GmbH	0483 - MDC medical device certification GmbH	31 December 2027
	D1016000045 D1016000058	06 November 2023			
Ref. 60052842 Gelatamp White 10x10x10 mm	D1016000036	29 August 2023	0483 - MDC medical device certification GmbH	0483 - MDC medical device certification GmbH	31 December 2027
	D1016000045 D1016000058	06 November 2023			