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Certified Quality System
ISO 13485:2016
Cert. n° D101600055
ISO 9001:2015
Cert. n° D1016000056

DECLARATION OF CONFORMITY

By the present document Mascia Brunelli Spa, with its legal address in Viale Monza 272 – 20128 MILANO, declares on our own responsibility, that the following medical devices made of gelatin sponge:

-	Ref 60052842	Gelatamp White	10 x 10 x 10mm	package of 24 pcs;
-	Ref 60036568	Gelatamp Forte	10 x 10 x 4mm	package of 24 pcs;

meet all applicable requirements of the Directive 93/42/EEC.

It is classified as Class III medical devices according to the rules 17 and 8 of the Directive 93/42/EEC Annex IX. The conformity assessment was performed according to Annex II.

Notify Body: mdc MEDICAL DEVICE CERTIFICATION GmbH – Kriegerstrasse 6 – 70191 Stuttgart - Germany – Ref. n° 0483.

EXP. DATE: 31 Dec 2027

Dr.ssa Beatrice Brunelli
MASCIA BRUNELLI S.p.A.

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Milan, 21 Mar 2024
Rev 00