Mascia Brunelli S.p.a.
Viale Monza, 272
20128 Milano - Italy
Tel +39 02.25.209.1
Fax +39 02.25.76.428
info@masciabrunelli.it
www.masciabrunelli.it

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

## DECLARATION OF CONFORMITY

By the present document Mascia Brunelli S.p.A., 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 0517050 | Cutanplast STANDARD x 300 | 50x70x10 mm | package of 300 pcs; |
| - | Ref 05170502 | Cutanplast STANDARD | 50x70x10 mm | package of 20 pcs; |
| - | Ref 05180502 | Cutanplast 80x50 | 80x50x10mm | package of 20 pcs |
| - | Ref 05200001 | Cutanplast POWDER | 1 gr | package of 6 pcs; |
| - | Ref 05200005 | Cutanplast POWDER 5g | 5 gr | package of 1 pc; |
| - | Ref 05230302 | Cutanplast DIAL | 30x30x10mm | package of 20 pcs; |
| - | Ref 05380502 | Cutanplast SPECIAL | 50x70x1 mm | package of 20 pcs; |
| - | Ref 05480301 | Cutanplast ANAL x 5 | 80x30 mm | package of 5 pcs; |
| - | Ref 05480302 | Cutanplast ANAL | 80x30 mm | package of 20 pcs; |
| - | Ref 05520602 | Cutanplast 20x60 | 20x60x7 mm | package of 20 pcs; |
| - | Ref 05580202 | Cutanplast 80x20 | 80x20x10 mm | package of 20 pcs |
| - | Ref 05610101 | Cutanplast DENTAL | 10x10x10mm | package of 24 pcs; |
| - | Ref 05621031 | Cutanplast DENTAL Ogna | 10x10x10 mm | package of 24 pcs; |
| - | Ref 05770202 | Cutanplast FILM | 70x200x0.5 mm | package of 20 pcs; |
| - | Ref 05770203 | Cutanplast FILM x50 | 70x200x0.5 mm | package of 50 pcs |
| - | Ref 05850302 | Cutanplast SMALL | 50x30x10mm | package of 20pcs; |
| - | Ref 058801251 | Cutanplast LARGE | 80x125x10mm | package of 10 pcs; |
| - | Ref 07150501 | Cutanplast FAST 50x50 | 50x50x4 mm | package of 10 pcs |
| - | Ref 07170701 | Cutanplast FAST 70x70 | 70x70x4 mm | package of 10 pcs |
| - | Ref 07200001 | Cutanplast FAST Powder 1gr | 1 gr | package of 6 pcs |
| - | Ref 07200005 | Cutanplast FAST Powder 5 gr | 5 gr | package of 1 pc |
| - | Ref 07610101 | Cutanplast FAST Dental | 10x10x4 mm | package of 24 pcs |
| - | Ref 07880125 | Cutanplast FAST 80x125 | 80x125x4 mm | package of 10 pcs |

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

They are 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.



Mascia Brunelli Spa
Viale Monza 272 - 20128 Milano
Tel 02.252091
C.F e P.IVA 05985320158

Milan 20 Mar 2024
**Rev. 18**