



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 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: 26 May 2024

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