



PRODUCTION S.p.A.

Via delle Poste 16 - 14010 Dusino San Michele AT (Italy) Tel. 0141979911 – Fax 0141979900

DF-Q02

Rev. 8 – date 23/09/16

**Declaration of conformity of the medical device denominated
“SINGLEFIX READY TO USE DRESSING FOR ONE FINGER”
manufactured by the Company FRA Production S.p.A.**

The undersigned Company FRA PRODUCTION S.p.A., with head office in Dusino San Michele (AT) Italy - Via delle Poste, 16, manufacturer of the above-mentioned device, declares under its own responsibility that the device in object satisfies all applicable dispositions in the Directive 93/42/CEE (acknowledged with D.Lgs. n° 46 of the 24.02.97) AS MODIFIED IN THE Directive 2007/47/CEE (acknowledged with D.Lgs. n° 37 of the 25/01/10).

To such a purpose the undersigned guarantees and declares under its own responsibility the following:

- the device in object satisfies the essential requisites required by enclosure I of the Directive 93/42/CEE;
- the device in object is to be considered as belonging to class I;
- the device in object IS NOT A MEASURING DEVICE;
- the device in object IS NOT DESTINED TO CLINICAL INVESTIGATIONS;
- the device in object IS SOLD IN A **STERILE WRAPPING**;
 - that the sterilization is carried out by ionizing radiations;
 - that the sterilization is made by the Company:
STERIS S.p.A. (ex BIOSTER)
Via Cà Bertoncina 29
24068 – Seriate (BG) – Italy
- that the sterilization process is carried out according to the Quality System for which the authorization of the Ministry of Health, General Management of the Pharmaceutical Service, V division with letter No. 800.5.OFF.1202/3683.4 of the 02/02/1994, has been obtained.

We declare, finally, that FRA Production SPA will keep available for the Sanitary Authority the documentation specified in enclosure VII of the Directive 93/42/CEE for a period of 8 years from the last manufacturing date of the device in object.

FRA PRODUCTION SPA
CEO – Andrea Colombo

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