



PRODUCTION S.p.A.

Fraz. S. Matteo Fondo 38 – 14010 Cisterna d’Asti (Italy) – Tel. 0141979911 – Fax 0141979900

DF-P02

Rev. 5 – Data 12/01/15

Declaration of Conformity of the device in polyester denominated “**SURGIFIX**” manufactured by the Company **FRA PRODUCTION S.p.A.**

The undersigned Company FRA PRODUCTION S.p.A., with head office in Cisterna d’Asti Italy, Frazione San Matteo Fondo 38, 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 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 wrapping non-sterile;

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  
Amministratore Delegato  
Dr. Andrea Colombo

COLORLINE  
**surgifix® euronet®**

**ecottonbag®**

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Identification Number/Numero di Identificazione: IT00104400056 www.fraproduction.it



UNI CEI EN 13485  
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