COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 13485

COMPANY WITH
QUALITY SYSTEM
CERTIFIED BY DNV
ISO 9001

BIO SUD MEDICAL SYSTEMS S.R.L.
PRODOTTI E SISTEMI PER LA MEDICINA

S.r.l. Cap. Sociale € 52.000,00 i.v.
C.F./P.IVA 03225090723 VAT IT03225090723
Reg. Impr. N. 03225090723 N. iscrizione REA 249474 CCIAA di Bari

Via dei Fabbri, 23/25 – Zona Artig. ASI
70026 Modugno (BA) ITALIA
Tel. ++39 080 5355669 - Fax ++39 080 5321061
Mail: info@biosud.it PEC : biosudbari@pec.it
Website: www. biosud.it - www.biomedsurgical.eu

DECLARATION OF CONFORMITY

BIO SUD MEDICAL SYSTEMS S.r.l. headquartered in Modugno (BA), Via dei Fabbri 23/25, ITALY, MANUFACTURER of the Medical Device:

COMMERCIAL NAME: BIOFELT

intended to be used as general reinforcement of suture points and suture support (pledget)

DECLARES

On its own responsability, that the Medical device in question satisfies all the Essential Requirements mentioned in Annex I of 93/42/ECC Directive of Medical Devices and any subsequent amendments and additions.
For this purpose, it guarantees and declares on its own responsability as follows:
- that the Medical Device in question satisfies the applicable provisions of 93/42/ECC Directive of Medical Devices and any subsequent amendments and additions, transposed into national legislation by Legislative Decree 24th February1997, n. 46 and any subsequent amendments;
- that the Medical device in question is classified in Class III;
- that the Medical Device in question is provided STERILE;
- that the Medical Device is compliant with Essential Requirements and provisions of 93/42/EEC Directive of Medical Devices and any subsequent amendments and additions;
- that the Medical Device is manufactured according to the Quality System, that satisfies the Annex II's requirements of the above mentioned Legistative Decree, as indicated in the CE Certificate: Product Design Examination n. EPG-0160-18 (Expiry date 31/12/2027) and EC Declaration of Conformity Full Quality Assurance System n. QCT-0087-18 (Expiry date 31/12/2027), issued by"Istituto Superiore di sanità – Notified Body n.0373".

The manufacturer also declares to have established and maintain an appropriate procedure to guarantee the post-market surveillance, required by 93/42/ECC Directive and any subsequent amendments and additions.

The declarant

(Nicola Ribatti – President of B.o.D.)
Bio Sud Medical Systems S.r.l.