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: BIOLENE

intended to be used as surgical non absorbable suture

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-0161-18 (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.