

B. Braun Surgical, S.A.
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Global Declaration of Conformity

We, on behalf of **B. Braun Surgical, S.A.**, herewith confirm that we have established and are maintaining a quality management system according to

EN ISO 13485: 2016
(Certificate Registration No.: Q5 025701 0085 Rev.04)

for the following area,

Design and Development, Production, Storage, Sales and Distribution of Medical Devices: Sterile absorbable and non absorbable sutures and microsutures with and without needles, combined and non combined with medicinal substances and accessories, Sterile surgical tapes, Sterile surgical meshes combined and non combined with medicinal substances, Surgical stapler, Local haemostatic agents, Absorbable implants for filling of bone defects, Tissue adhesives and accessories, Wound care Products for Vacuum Therapy, Accessories for suturing techniques, Sterile Suture Procedure packs.

Furthermore, we have implemented the conformity assessment procedure as per Annex II, clause 3 of the Medical Device Directive 93/42/EEC of June 14th, 1993 concerning medical devices.

EC Certificate No.: G1 025701 0090 Rev.01

Issued by the Notified Body **TÜV SÜD Product Service GmbH (NB No. 0123)**, Ridlerstrasse 65, 80339 Munich, Germany.

We declare that the products of the attached list meet the provisions of the Council Directive 93/42/EEC for Medical Devices.

To complete the present declaration, this document is approved and signed in **Rubí**, on **November 18th, 2020**.

Silvia Orús
Global Regulatory Affairs Manager
CoE, Closure Technologies
B. Braun Surgical, S.A.

Dr. Pau Turon, PhD (Chem), PhD (B.AdM.)
VP Research and Development
B. Braun Group (Spain)

Effective

Attached list: Products with EC Certificate:

Class I	Class III
Histoacryl Tip	Dafilon (USP 8/0 to 11/0) (Microsutures)
OP-Magnet	Gelita-Tampon
Class IIa	Histoacryl
Dafilon (USP 5 to 7/0)	Lyostypt
Endo-Sponge	MonoMax
Eso-Sponge	Monoplus
Histoacryl Applicator - Open Hernia Repair	Monosyn
Histoacryl Flexible	Monosyn Quick
Manipler AZ	Novosyn
Securex	Novosyn Quick
Supramid	Novosyn CHD
Surgical Loop	Optilene
Histoacryl Lapfix Cannula	Optilene Silver Mesh LP
Class IIb	Optilene Silver Mesh Elastic
Bone Wax	Premilene
Dagrofil	Premipatch PTFE Pledgets
Flexocrin	Premicron
Optilene Mesh	Safil
Optilene Mesh Elastic	Safil Parenchyma Set
Optilene Mesh LP	Safil-Mesh
Patella-Set	Safil-Mesh Kidney Bag
Premilene Mesh	Safil-Mesh Spleen
Premilene Mesh Plug	Sangustop
Silkam	Steelex Electrode Set
Steelex	
Steelex Sternum Set	
Trelon	

Title: Global Declaration of Conformity Initiator: Maria ? Gutierrez

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Calderone, Vittorio (caldvae)

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Meaning: Document signed as Author

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Date: Tuesday, 24 November 2020, 09:58 W. Europe Daylight Time

Meaning: Approve Document

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