

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.05)

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 medical 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, B. Braun Surgical, S.A. is EC certified according to:

Directive 93/42/EEC on Medical Devices (MDD) Annex II excluding (4) (Devices in class IIa, IIb or III)
No. G1 025701 0090 Rev. 01
Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Implantable class IIb Devices and class III Devices) No. G12 025701 0096 Rev. 01
Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (class IIa and Class IIb devices) No. G10 025701 0095 Rev. 00

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 and/or the Regulation (EU) 2017/745 on Medical Devices as detailed in the list.

To complete the present declaration, this document is approved and signed in Rubí, on January 10, 2024.



Sílvia Orús
Global Regulatory Affairs Manager
CoE, Operating Room Supply
B. Braun Surgical, S.A.



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

Attached list:

Products with EC Certificate according to Council Directive 93/42/EEC

Class I
Histoacryl Tip OP-Magnet
Class IIa
Dafilon (USP 5 to 6/0) Endo-Sponge Endo-Sponge Fistula Eso-Sponge Histoacryl Flexible Manipler AZ Supramid Surgical Loop cotton Surgical Loop silicone Histoacryl Lapfix Cannula
Class IIb
Bone Wax Dagrofil Optilene Mesh Optilene Mesh Elastic Optilene Mesh LP Premilene Mesh Premilene Mesh Plug Silkam Steelex Sternum Set

Class III
Dafilon (USP 8/0 to 11/0) (Microsutures) Histoacryl Lyostypt MonoMax Monosyn Monosyn Quick Novosyn Novosyn Quick Optilene Premipatch PTFE Pledgets Premicron Safil-Mesh Sangustop Steelex Electrode Set

Products with EC Certificate according to Regulation (EU) 2017/745 on Medical Devices

Class III
Monoplus Novosyn CHD Histoacryl

Class IIa
Endo-Sponge Eso-Sponge