

B. Braun Surgical, S.A. Carretera de Terrassa, 121 08191 Rubí (Barcelona) Tel.: 93 586 62 00* Fax: 93 588 10 96 www.bbraun.es

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	Class III
Histoacryl Tip	Dafilon (USP 8/0 to 11/0) (Microsutures)
OP-Magnet	Histoacryl
Class IIa	Lyostypt
Dafilon (USP 5 to 6/0)	MonoMax
Endo-Sponge	Monosyn
Endo-Sponge Fistula	Monosyn Quick
Eso-Sponge	Novosyn
Histoacryl Flexible	Novosyn Quick
Manipler AZ	Optilene
Supramid	Premipatch PTFE Pledgets
Surgical Loop cotton	Premicron
Surgical Loop silicone	Safil-Mesh
Histoacryl Lapfix Cannula	Sangustop
Class IIb	Steelex Electrode Set
Bone Wax	
Dagrofil	
Optilene Mesh	
Optilene Mesh Elastic	
Optilene Mesh LP	
Premilene Mesh	
Premilene Mesh Plug Silkam	
Steelex Sternum 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