ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 16 03 25701 065

Manufacturer: **B. Braun Surgical S.A.**
Ctra. de Terrassa, 121
08191 Rubi (Barcelona)
SPAIN

Product: **Sutures / Meshes / Tape**

Model(s):
Safil®
Safil® Mesh
Safil® Mesh Kidney Bag
Safil® Mesh Spleen Bag
Safil® Parenchyma Set

Parameters:

Suture:
Polyglycolic acid suture, braided, coated, absorbable undyed in the natural beige colour, violet and Polyglycolic acid uncoated monofilament

Mesh:
Polyglycolic acid mesh, uncoated, absorbable undyed in the natural beige colour with coated violet or undyed Holding threads for the bags

Tape:
Polyglycolic acid woven tape, uncoated, absorbable violet

see attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf.

Report no.: 713079522
Valid from: 2016-10-18
Valid until: 2021-07-25

Date, 2016-10-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

Product Service

Attachment to Certificate no G7 16 03 25701 065
dated 2016-10-18

Safil®	USP Caliber 10/0 to 2	EP Caliber 0.2 to 5	Length max. 250 cm
Safil® Parenchyma Set	3mm x up to 90 cm		
Safil® Mesh Kidney Bag	15 x 8 cm		
Safil® Mesh Spleen Bag	26 x 30 cm		
Safil® Mesh	6 x 5 cm 8 x 2 cm 12 x 8 cm 15 x 15 cm 25 x 15 cm 28 x 18 cm 30 x 30 cm		

MHS-CRT, 2016-10-18

Stefan Preiß

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