Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7AO 025701 0092 Rev. 00

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

Product: **Collagen Implants**
Local Haemostyptic Agent

Model(s): **Lyostypt, Sangustop**

Parameters:

Article No.
1069600 Sangustop 5 cm x 3 cm (4 units)
1069500 Sangustop 5 cm x 8 cm (4 units)
1069550 Sangustop 5 cm x 8 cm (2 units)
1069400 Sangustop 5 cm x 8 cm (1 unit)
1069020 Lyostypt 5 x 8 cm
1069039 Lyostypt 10 x 12 cm
1069128 Lyostypt 3 x 5 cm
1069152 Lyostypt KHV 5 x 8 cm
1069209 Lyostypt KHV 10 x 12 cm
1069306 Lyostypt 5 x 30 cm

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 the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. See also notes overleaf.

Report no.: 713151596

Valid from: 2019-10-01
Valid until: 2024-05-26

Date, 2019-09-27

Stefan Preiß
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany