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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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 025701 0088 Rev. 00

Manufacturer:

B. Braun Surgical S.A.

Ctra. de Terrassa, 121
08191 Rubi (Barcelona)
SPAIN

Product:

Sutures

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.:

713142129

Valid from:

2019-05-27

Valid until:

2024-05-26

Date,

2019-05-24

Stefan Preiß

Head of Certification/Notified Body

EC Certificate

EC Design-Examination Certificate

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Facility(ies):

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

Model(s):

Monosyn

Parameter:

Glyconate suture, monofilament, absorbable,
undyed and violet, with or without loop

| USP Caliber | EP Caliber | Length |
|-------------|------------|------------|
| 7/0 to 2 | 0,5 to 5 | max. 250cm |