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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 0081 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.:

713124098

Valid from:

2018-09-18

Valid until:

2023-09-17

Date,

2018-09-13

Stefan Preiß

EC Certificate

EC Design-Examination Certificate

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

No. G7 025701 0081 Rev. 00

Facility(ies):

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

Model(s):

Optilene® non-absorbable, sterile surgical suture material made of polypropylene and polyethylene. Optilene® sutures are dyed blue with copper phthalocyanine [29H, 31H-Phthalocyaninato (2-)-N29, N30, N31, N32] Copper

Optilene is available from size USP 2 (5 metric) to size USP 10/0 (0.2 metric).

Length 8 to 240 cm.

There is a special presentation for Optilene with Premipatch® PTFE pledgets made from 100% polytetrafluoroethylene.