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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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. G7 025701 0058 Rev. 01

Manufacturer:

B. Braun Surgical S.A.

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

Product:

Sutures

Model(s):

PremiCron

PremiCron with PTFE Pledgets (6x3 mm, 3x3 mm)

Parameter:

Polyethylene terephthalate (PET), braided, non-absorbable
suture, available either white (undyed) or dyed green,
with or without pledgets.

Premicron available sizes
USP 6/0 (0.7 metric) to USP 5 (7 metric)

Maximum length: 250 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 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.:

713157798

Valid from:

2020-01-04

Valid until:

2024-05-26

Date,

2019-12-17

Christoph Dicks
Head of Certification/Notified Body

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