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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. G7 087339 0007 Rev. 01

Manufacturer:

PolyNovo Biomaterials Pty Ltd.

2/320 Lorimer Street
Port Melbourne VIC 3207
AUSTRALIA

Product:

**Wound Dressing
absorbable**

Model(s):

**Model(s): NovoSorb® BTM
Biodegradable Temporising Matrix**

Parameter:

Catalogue no.	Dimensions	Pack Size
BTM-1010	10 cm x 10 cm	1
BTM-1020	10 cm x 20 cm	1
BTM-2040	20 cm x 40 cm	1
BTM-0304	3 cm x 4 cm	1
BTM-0505	5 cm x 5 cm	1
BTM-0608	6 cm x 8 cm	1
BTM-2025	20 cm x 25 cm	1

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:G7_087339_0007_Rev.01

Report no.:

713207354

Valid from:

2021-04-21

Valid until:

2024-05-26

Date,

2021-04-21

Christoph Dicks
Head of Certification/Notified Body