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

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 070692 0028 Rev. 00

Manufacturer: **Greatbatch Medical**
2300 Berkshire Lane North
Minneapolis MN 55441
USA

EC-Representative: Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, GERMANY

Product Category(ies): **Percutaneous Introducer Systems and Safety Needles**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72144526

Valid from: 2019-04-03
Valid until: 2022-03-10

Date, 2019-04-03

I. Preuß

Stefan Preiß

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

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Facility(ies):

Greatbatch Medical
2300 Berkshire Lane North, Minneapolis MN 55441, USA

Greatbatch Medical, S. de R.L. de C.V.
Boulevard Hector Teran Teran 20120, Ciudad Industrial, Tijuana,
Baja California, 22444, MEXICO

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