



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



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 041538 0005 Rev. 00

Manufacturer:

Degania Silicone Limited

Kibbutz
1513000 Degania Bet
ISRAEL

Product Category(ies):

Identiloops, Silclamps, Urological Catheters and kits with accessories,
Gastrostomy & Feeding Tubes and kits with accessories, Surgical Drains and
kits with accessories, Sterile and non-sterile medical devices for general
surgery, chest drainage and custom made medical device components

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.:

IND2019062

Valid from:

2019-10-17

Valid until:

2024-05-26

Date,

2019-10-17

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 證 書 ◆ CERTIFICADO ◆ CERTIFICAT

