



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 17 12 41538 002

Manufacturer: Degania Silicone Limited

Kibbutz
1513000 Degania Bet
ISRAEL



EC-Representative: Biometrix s.r.o

Vicenzy 16S
93101 Samorin
SLOVAKIA

**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 medical device components
(Refer attachment for product details)

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.: IND2017046

Valid from: 2018-04-28

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Date, 2018-04-18

Stefan Preiß

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

Page 1 of 2



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Facility(ies):

Degania Silicone Limited
Kibbutz, 1513000 Degania Bet, ISRAEL

Shomrat Molds LTD
Industrial Zone, 1030000 Hatzor Haglilit, ISRAEL