



Certificate

No. Q5 041538 0009 Rev. 00

Holder of Certificate: **Degania Silicone Limited**
Kibbutz
1513000 Degania Bet
ISRAEL

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Sterile and Non-Sterile Medical Devices for General Surgery, Urology, Enteral Feeding and Custom Made Devices.**

Production and Distribution of Sterile and Non-Sterile Medical Devices for General Surgery, Chest Drainage and Custom Made Device Components

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 041538 0009 Rev. 00

Report No.: IND2020122

Valid from: 2021-08-06

Valid until: 2021-12-10

Date, 2021-08-06



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Degania Silicone Limited
Kibbutz, 1513000 Degania Bet, ISRAEL

see scope of certificate

Shomrat Molds LTD
Industrial Zone, 1030000 Hatzor Haglilit, ISRAEL

Injection molding of custom made plastic components for Medical
device

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