



Product Service

# CERTIFICATE

No. Q1N 17 12 41538 001

**Holder of Certificate:** **Degania Silicone Limited**

Kibbutz  
1513000 Degania Bet  
ISRAEL

**Facility(ies):**

Degania Silicone Limited  
Kibbutz, 1513000 Degania Bet, ISRAEL

Shomrat Molds LTD  
Industrial Zone, 1030000 Hatzor Haglilit, 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**

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012  
Upgrade required until 2019-03-31

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). See also notes overleaf.

**Report No.:** IND2017046

**Valid from:** 2018-04-28

**Valid until:** 2021-04-27

**Date,** 2018-04-18

Stefan Preiß

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DAKKS

Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00