



Product Service

CERTIFICATE

No. Q1N 16 03 76875 007

Holder of Certificate: SURGIKA S.r.l.

Via 2 Giugno 125
52025 LEVANE- BUCINE (AR)
ITALY

Facility(ies):

SURGIKA S.r.l.
Via 2 Giugno 125, 52025 LEVANE- BUCINE
(AR), ITALY

Certification Mark:



Scope of Certificate:

**Design, manufacturing and/or manufacture management, distribution of: medical devices in non woven and synthetic material for surgical theatre;
medical devices for infusion management in critical area,
in surgical theatre and in oncology;
custom packs for surgical application;
single use medical devices for local area anaesthesia
and elastomeric pumps**

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

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.: ITA269118

Valid from: 2016-03-30

Valid until: 2019-03-29

Date, 2016-03-30

S. Preiß
Stefan Preiß

