



Product Service

CERTIFICATE

No. Q1N 17 02 96207 001

Holder of Certificate: **Clinisut Pty Ltd**
25 Harrower Road, North End
Port Elizabeth
6001 SOUTH AFRICA

Facility(ies): Clinisut Pty Ltd
25 Harrower Road, North End, Port Elizabeth,
6001 SOUTH AFRICA

**Certification Mark:**

Scope of Certificate: Design, Development, production and distribution of sterile Synthetic absorbable sutures with and without needle (Model: PGA, PGA Rapid, PDO, PGCL) and non-absorbable sutures with and without needle (Model: PVDF, Silk, Nylon, Polyester, Polypropylene and Linen) for surgical use.

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.: IND2016038

Valid from: 2017-02-24
Valid until: 2020-02-23



Date, 2017-02-24

Stefan Preiß

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