



Product Service

Certificate

Q5 037539 0017 Rev. 01

Holder of Certificate: **Dignitana AB**

Traktorgränden 3
226 60 Lund
SWEDEN

Facility(ies):

Dignitana AB
Traktorgränden 3, 226 60 Lund, SWEDEN

Certification Mark:



Scope of Certificate:

Design and development, production, distribution, sales and servicing of scalp-cooling devices with accessories

Applied Standard(s):

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

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.: 713165509

Valid from: 2020-04-15

Valid until: 2022-11-30

Date, 2020-04-15

Christoph Dicks
Head of Certification/Notified Body