



Certificate

No. Q8 037539 0016 Rev. 02

Holder of Certificate: **Dignitana AB**

Traktorgränden 3
226 60 Lund
SWEDEN

Facility(ies):

Dignitana AB

Traktorgränden 3, 226 60 Lund, SWEDEN

See Scope of Certificate

Dignitana, Inc.

10925 Estate Lane, W185, Dallas TX 75238, USA

See Scope of Certificate

Certification Mark:



Scope of Certificate:

The provision of Sales, Distribution and Servicing for 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). 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:Q8 037539 0016 Rev. 02

Report No.: 713266330

Valid from: 2022-12-01

Valid until: 2025-11-30

Date, 2022-12-01



Christoph Dicks
Head of Certification/Notified Body

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|----------------------|--|--------------------------------------|------------------------------|
| | Category: REC Title: ISO 13485 Q8 Certificate | | |
| Version 01 | State Effective | Effective Date 02-DEC-2022 | Document ID 770645 |

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REVISION HISTORY

Version 01 Effective on 02-Dec-2022

Initial

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

Anders Carlsson
anders.carlsson@dignitana.com

I am the author of this document.
Signed 8:34:42 AM UTC 02-Dec-2022

Additional Steps Added

Niklas Lindgren
VP QA/RA
niklas.lindgren@dignitana.com

I have reviewed and approve this document.
Signed 8:38:26 AM UTC 02-Dec-2022