Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 037539 0010 Rev. 01

Manufacturer:

Dignitana AB
Traktorgränden 3
226 60 Lund
SWEDEN

Facility(ies):

Dignitana AB
Traktorgränden 3, 226 60 Lund, SWEDEN

Product Category(ies): **Scalp-cooling devices with related accessories (cooling caps)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713163421

Valid from: 2019-10-06
Valid until: 2024-05-26

Date, 2019-10-02

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

REVISION HISTORY

Version 01 Effective on 16-Nov-2022
Initial

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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I am the author of this document.
Signed 9:58:05 AM UTC 16-Nov-2022

Additional Steps Added

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I have reviewed and approve this document.
Signed 10:22:32 AM UTC 16-Nov-2022