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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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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

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Valid until: 2024-05-26

Date, 2019-10-02

Stefan Preiß
Head of Certification/Notified Body