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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 036048 0005 Rev. 00

Manufacturer: Novafon GmbH
Daimlerstrasse 13
71384 Weinstadt
GERMANY

Facility(ies): Novafon GmbH
Daimlerstrasse 13, 71384 Weinstadt, GERMANY

Product Category(ies): Active local vibration devices for rehabilitation

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.

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Stefan Preiß