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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03



Product Service

EC Certificate

EC Design-Examination Certificate

Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 017853 0140 Rev. 02

Manufacturer:

MED-EL

Elektromedizinische Geräte GmbH

Fürstenweg 77A
6020 Innsbruck
AUSTRIA

Product:

Implantable Hearing Prosthesis Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.:

713168127

Valid from:

2020-05-25

Valid until:

2024-05-26

Date,

2020-05-25

Christoph Dicks

Head of Certification/Notified Body

TÜV SÜD
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Model(s): Vibrant Soundbridge®
(see below)

Product: Implantable Hearing Prosthesis Systems

Test Report No.: 71353685

Model:	Model no.:
Vibrating Ossicular Prosthesis (right ear)	VORP 502A
Vibrating Ossicular Prosthesis (left ear)	VORP 502B
Application Software (ext.)	SYMFIT

Test Report No.: 71364327

Model:	Model no.:
Vibroplasty Coupler	Vibroplasty-OW-Coupler Vibroplasty-Clip-Coupler Vibroplasty-Bell-Coupler Vibroplasty-RW-Coupler

Test Report No.: 713040664

Model:	
Vibroplasty Coupler	Incus-LP-Coupler, left Incus-LP-Coupler, right RW-Soft-Coupler Incus-SP-Coupler Incus-Symphonix-Coupler, left Incus-Symphonix-Coupler, right

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No. I7 017853 0140 Rev. 02

Test Report No.: 713044247

Model:

Model no.:

Vibrating Ossicular Prosthesis

VORP 503 Implant Kit*

VORP 503 Sizer Kit

(*implantable components with conditional use in MRI environment)

Test Report No.: 713048872

Model:

Model no.:

Audio Processor

SAMBA Lo

Audio Processor

SAMBA Hi

Remote Control

Test Report No.: 713066560

Model:

Model no.:

Application Software (ext.)

SYMFIT BAO

Test Report No.: 713160249

Model:

Model no.:

Application Software (ext.)

SYMFIT 8.x

Test Report No.: 713160251

Model:

Model no.:

Audio Processor

SAMBA 2 Hi

Audio Processor

SAMBA 2 Lo

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Test Report No.: 713168127

Model:

Vibroplasty Coupler

Model no.:

Stapes-SH-Coupler