

Declaration of Conformity

The signatory, who represents the below-mentioned manufacturer,

Manufacturer:

Otto Bock Healthcare Products GmbH
Brehmstraße 16
A-1110 Wien, Austria

here with declares that the products included in appendix I are conform to the relevant provisions of the below-mentioned EC Directive.

93/42/EEC Directive of the Council dated June 14th 1993 for the Adjustment of Regulation for Member States regarding Medical Devices.

Notified Body: N.A.

Notified Body Address: N.A.

Notified Body Number: N.A.

The conformity is declared based on Appendix VII of the Directive 93/42/EEC considering the amendments by the directive 2007/47/EC.

Valid through: 2020-11-04 (YYYY.MM.DD)

This declaration is valid for all products of the above design that are fabricated according to the respective fabrication documents.

Wien, Vienna 2018-11-05

Lieu, Date


DI Hans Heinz Antonius Richartz
(Managing Director)


Dr. Hans-Willem van Vliet
(Vice President R&D)


DI(FH) Reinhard Wolkerstorfer
(Head of Regulatory Affairs)

Otto Bock Healthcare Products GmbH

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Quality for life

Appendix I – Medical Devices (acc. to EU MDD 93/42/EC)

All the medical devices of legal manufacturer belong to one or more of the following products groups and are conform to the European Medical Device Directive as stated in the Declaration of Conformity.

UMDNS	UMDNS Term
11-441	Electrodes, Electromyographic
13-134	Prostheses, Arm
13-150	Prostheses, Lower Limb, Foot
13-151	Prostheses, Upper Limb, Hand
13-160	Prostheses, Leg
13-168	Prostheses, Joint, Wrist
16-105	Prosthesis, Joint, Elbow
16-337	Batteries, Medical Devices
17-115	Battery Chargers
17-859	Orthoses, Leg
23-365	Prostheses, Upper Limb, Hand, Myoelectric
23-383	Prostheses, Upper Limb, Elbow
23-411	Prostheses, Lower Limb, Total