

## Declaration of Conformity

The signatory, who represents the below-mentioned manufacturer,

**Manufacturer:**

Ottobock SE & Co. KGaA  
Max-Näder-Strasse 15  
D-37115 Duderstadt

herewith declares that the products listed in appendix I are conform to the relevant provisions of the below-mentioned EC Directive.

**93/42/EEC** Council Directive 93/42/EEC of 14 June 1993 concerning 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.

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

**Duderstadt 2018-04-03**

**Date**

Management CTO

Dr. Andreas Goppelt

Chief Sales & Marketing  
Officer (CSMO)

Ralf Stuch

Head of Regulatory Affairs

Dominik Schmidt



Quality for life

## Appendix I - Medical Devices

All medical devices of the legal manufacturer are registered under one or more of the following products groups (UMDNS).

UMDNS	UMDNS Term	Description
17-873	Orthosis, foot/ankle	
17-874	Orthosis, knee	
17-930	Orthosis, hip	
17-909	Orthosis, back	
n.a.	Orthosis, neck	Orthosis for rehabilitation of the cervical spine
17-872	Orthosis, arm	
17-911	Orthosis, wrist	
13-150	Prosthesis, foot	
n.a.	n.a.	Modular adapter for modular-prosthetic-systems of the lower extremities
13-158	Prosthesis, joint	
13-160	Prosthesis, leg	
n.a.	n.a.	liner from silicone or pu-gel to increase the wearing comfort of the modular prosthetic systems
n.a.	n.a.	Otto Bock Harmony System – negative pressure system for modular-leg-prostheses to improve the adhesion between stump and socket.
n.a.	n.a.	Foam layer for cosmetically coverage of modular-prosthetic-systems
13-151	Prosthesis, hand	
13-168	Prosthesis, joint, wrist	
16-099	Prosthesis, joint, shoulder	
13-134	Prosthesis, arm	
n.a.	n.a.	joints and splints to build leg-orthoses
n.a.	n.a.	construction kit for torso-orthoses