

Declaration of Conformity

The signatory, who represents the below-mentioned manufacturer,

Manufacturer:

Otto Bock Mobility Solutions GmbH
Lindenstraße 13
D-07426 Königsee, Germany

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: 2021-05-25 (YYYY.MM.DD)

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

Königsee, 2021-01-08

Date



Ralf Theisen
(Managing Director)

p.p.



Björn Kölle
(Regulatory Affairs Manager)



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. The medical devices have been assigned to class I according to Annex IX of the Directive 93/42/EC.

UMDNS	UMDNS Term	Description
10-184	Arm Boards	Wheelchair accessories
10-801	Chairs, Rehabilitation	Rehabilitation aids, rehabilitation aids for kids
11-100	Cushions, Wheelchair	Seat cushion
11-964	Headrests	Wheelchair accessories
12-315	Leg Rests	Wheelchair accessories
13-355	Restraints, Vest	
13-356	Restraints, Wheelchair Occupant	
13-609	Bath-Seat	Bathing and care aids
14-449	Wheelchairs	Wheelchair accessories, Seating plate
15-214	Cushions, Other	Seating components
16-214	Wheelchairs, Powered	Power wheelchair and adaptations
16-949	Wheelchairs, Nonpowered	Manual wheelchairs
17-620	Wheelchairs, Nonpowered, Lightweight	Lightweight wheelchairs
17-630	Walkers, Wheeled	Walking aids, Anterior walker, Components for walkers
17-952	Power Conversion Kits, Wheelchair	Electrical adaptations
17-982	Standing Frames	
18-010	Backrests, Wheelchair	Wheelchair accessories
18-028	Supports, Upper-Extremity	Wheelchair accessories
(-)	Wheelchair accessories	Tires, Tubes, Castor wheels, Rear wheels, Crutch holder, Anti-tipper, Lap tray, Push handles, Clothing protector, Clamping lever, Toilet bucket