

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002 DECLARATION OF CONFORMITY PROCEDURES

This is declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's name: Otto Bock Healthcare Products GmbH
Business address: Brehmstraße 16
 1110 Vienna
 Austria
Medical device(s): See attached schedule
Classification: Class I
GMDN code and term: See attached schedule
Scope of application: All included articles in attached schedule

Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Standards applied: EN ISO 13485 Medical devices – Quality management systems
 – Requirements for regulatory purposes

Vienna, 2023-03-23 (YYYY-MM-DD)

Place, Date


 Andreas Eichler
 Managing Director


 DI(FH) Reinhard Wolkerstorfer
 Head of Regulatory Affairs

Article Number	Product Name	GMDN No	GMDN Term
10S17	Electric Wrist Rotator	41091	Myoelectric wrist prosthesis
12K100N*	DynamicArm	41100	Myoelectric elbow prosthesis
12K110N*	DynamicArm Plus	41100	Myoelectric elbow prosthesis
12K41*	ErgoArm	41100	Myoelectric elbow prosthesis
12K42*	ErgoArm plus	41100	Myoelectric elbow prosthesis
12K44*	ErgoArm Hybrid plus	41100	Myoelectric elbow prosthesis
12K50*	ErgoArm Electronic plus	41100	Myoelectric elbow prosthesis
12K501*	AxonArm Ergo	41100	Myoelectric elbow prosthesis
12V10	Tube Valve for Suction Socket	41497	Myoelectric hand prosthesis
13E100*	AnalogAdapter	41497	Myoelectric hand prosthesis
13E200*	Electrode	41497	Myoelectric hand prosthesis
13E202*	Suction Socket Electrode	41497	Myoelectric hand prosthesis
13E205	MyoRotronic	41091	Myoelectric wrist prosthesis
13E400*	Remote Electrode	41497	Myoelectric hand prosthesis
13E401*	Remote Electrode	41497	Myoelectric hand prosthesis
13E500*	AxonMaster	41497	Myoelectric hand prosthesis
13E520*	Myo Plus TR	41497	Myoelectric hand prosthesis
17CF2*	Spring Element	41065	Knee orthosis
17K01*	C-Brace joint unit	41065	Knee orthosis
17K01A=SET	Correction adapter set	41065	Knee orthosis
1B1-2*	Meridium	64725	Mechatronic external ankle-foot prosthesis
21A47*	Transhumeral Soft Harness	41490	Transhumeral prosthesis
2R17*	AXON Tube Adapter	61229	External lower limb prosthesis structural/alignment component
2R19*	AXON Tube Adapter	61229	External lower limb prosthesis structural/alignment component
2R20*	AXON Tube Adapter	61229	External lower limb prosthesis structural/alignment component
2R21*	AXON Tube Adapter with Torsion	61229	External lower limb prosthesis structural/alignment component
2R67*	Tube adapter with torsion unit, Ø34 mm	61229	External lower limb prosthesis structural/alignment component
2R81*	C-Leg Tube Adapter with Torsion Unit	61229	External lower limb prosthesis structural/alignment component
2R82*	C-leg Tube Adapter	61229	External lower limb prosthesis structural/alignment component
3B1-3*	Genium	64721	Mechatronic external knee prosthesis
3B5-3*	Genium X3	64721	Mechatronic external knee prosthesis
3C60*	Kenevo	64721	Mechatronic external knee prosthesis
3C88-3*	C-Leg	64721	Mechatronic external knee prosthesis
3C98-3*	C-Leg	64721	Mechatronic external knee prosthesis
3F1=1	Functional Cosmesis C-Leg	64736	External limb prosthesis finishing component, non-customized
3F1=1-N	Functional Cosmesis C-Leg (Knee Part)	64736	External limb prosthesis finishing component, non-customized
3F1=2	Functional Cosmesis Genium	64736	External limb prosthesis finishing component, non-customized
3F1=2-N	Functional Cosmesis Genium (Knee Part)	64736	External limb prosthesis finishing component, non-customized
4E50-2*	Battery Charger for C-Leg	17115	Noninvasive device battery charger
4E50-3*	Battery Charger for C-Leg	17115	Noninvasive device battery charger
4E60*	Inductive Charger	17115	Noninvasive device battery charger
4E70*	Inductive Charger	17115	Noninvasive device battery charger
4E70-1*	Inductive Charger	17115	Noninvasive device battery charger
4P862	C-Leg Guard	64736	External limb prosthesis finishing component, non-customized
4P863*	Shield insert	64736	External limb prosthesis finishing component, non-customized
4R110	Lamination anchor for children	61229	External lower limb prosthesis structural/alignment component

Article Number	Product Name	GMDN No	GMDN Term
4R112*	Sliding Adapter Set	61229	External lower limb prosthesis structural/alignment component
4R120	DeltaTwist	61229	External lower limb prosthesis structural/alignment component
4R121*	DeltaTwist	61229	External lower limb prosthesis structural/alignment component
4R39	Torsion Adapter	61229	External lower limb prosthesis structural/alignment component
4R40	Torsion Adapter	61229	External lower limb prosthesis structural/alignment component
4R57*	Rotation Adapter	61229	External lower limb prosthesis structural/alignment component
4R57=WR*	Rotation adapter	61229	External lower limb prosthesis structural/alignment component
4R85	Torsion Adapter	61229	External lower limb prosthesis structural/alignment component
4R86	Torsion Adapter	61229	External lower limb prosthesis structural/alignment component
4X1=V1.10	X-Soft 1.10	64734	External limb prosthesis adjustment software
4X154=V1.4	M-Soft 1.4	64734	External limb prosthesis adjustment software
4X160*	C-Leg Protector	64736	External limb prosthesis finishing component, non-customized
4X180=V2.8	C-Soft 2.8	64734	External limb prosthesis adjustment software
4X193-1*	Genium X3 Protective Cover	64736	External limb prosthesis finishing component, non-customized
4X440=V1.10	C-Soft Plus 1.10	64734	External limb prosthesis adjustment software
4X440=V1.8	C-Soft Plus 1.8	64734	External limb prosthesis adjustment software
4X441-V2=*	Cockpit	64734	External limb prosthesis adjustment software
4X445=V1.4	K-Soft 1.4	64734	External limb prosthesis adjustment software
4X445=V1.6	K-Soft 1.6	64734	External limb prosthesis adjustment software
4X840	Kenevo Protective Cover	64736	External limb prosthesis finishing component, non-customized
4X860*	C-Leg Protective Cover (w/o shield)	64736	External limb prosthesis finishing component, non-customized
4X900*	Genium X3 Protective Cover	64736	External limb prosthesis finishing component, non-customized
560X12=V1.4	bebalance+ 1.4	64734	External limb prosthesis adjustment software
560X12=V1.6	bebalance+ 1.6	64734	External limb prosthesis adjustment software
560X17-*=V1.2	C-Brace Setup	41065	Knee orthosis
560X18-*=V1.2	Myo Plus	64734	External limb prosthesis adjustment software
560X23-V1=*	Kenevo A-B-C	64734	External limb prosthesis adjustment software
560X3=V1.0	MyolinoSoft	64734	External limb prosthesis adjustment software
560X500=V2.2	AxonSoft 2.2	64734	External limb prosthesis adjustment software
5A60=*	Varos	64713	External lower-limb prosthesis socket, non-customized
60X3*	BionicLink	64721	Mechatronic external knee prosthesis
60X6	MyolinoLink	41497	Myoelectric hand prosthesis
60X7	BionicLink	41065	Knee orthosis
646C42=V1.6	ElbowSoft 1.6	64734	External limb prosthesis adjustment software
646C52=V1.2	PAULA 1.2	64734	External limb prosthesis adjustment software
646C57=V1.4	ElbowSoft TMR 1.4	64734	External limb prosthesis adjustment software
757B20*	EnergyPack	34158	Secondary battery
757B21*	EnergyPack	34158	Secondary battery
757B35=0*	MyoEnergy Integral	34158	Secondary battery
757B35=1	MyoEnergy Integral	34158	Secondary battery
757B35=3	MyoEnergy Integral	34158	Secondary battery
757B35=4*	MyoEnergy Integral	34158	Secondary battery
757B35=5*	MyoEnergy Integral	34158	Secondary battery
757B501*	AxonEnergy Integral	34158	Secondary battery
757L35*	MyoCharge Integral	17115	Noninvasive device battery charger
757L500*	AxonCharge Integral	17115	Noninvasive device battery charger
757M11=2	MyoBoy Light	41497	Myoelectric hand prosthesis
757M20*	Myo Cuff	41497	Myoelectric hand prosthesis

Article Number	Product Name	GMDN No	GMDN Term
8E3*=9*	System Electric Greifer DMC VariPlus	41084	Split-hook/specialized-tool hand prosthesis
8E**=6*	System Electric Hand DMC plus	41497	Myoelectric hand prosthesis
8E**=7*	System Electric Hand Digital Twin	41497	Myoelectric hand prosthesis
8E**=8*	SensorHand Speed / SensorHand Speed Flex	41497	Myoelectric hand prosthesis
8E**=9*	MyoHand VariPlus Speed	41497	Myoelectric hand prosthesis
8E44=6*	Transcarnal Hand DMC plus	41497	Myoelectric hand prosthesis
8E500*	Michelangelo Hand	41497	Myoelectric hand prosthesis
8E51*	Electric Hand 2000	41497	Myoelectric hand prosthesis
8E550*	Michelangelo Hand Transcarnal	41497	Myoelectric hand prosthesis
8E600*	AxonHook	41084	Split-hook/specialized-tool hand prosthesis
8E70*	bebionic Hand EQD	41497	Myoelectric hand prosthesis
8E71*	bebionic Hand Short Wrist	41497	Myoelectric hand prosthesis
8E72*	bebionic Hand Flex	41497	Myoelectric hand prosthesis
8K50*	MyoFacil	41497	Myoelectric hand prosthesis
8R1*	Endoskeletal Adapter	41086	Passive wrist prosthesis
99B120*	Functional Stocking	64736	External limb prosthesis finishing component, non-customized
9E420*	7in1 Controller	41497	Myoelectric hand prosthesis
9S501*	AxonRotation Adapter	41086	Passive wrist prosthesis
9S503*	AxonRotation	41091	Myoelectric wrist prosthesis
9X14	Harness Pull Switch	41099	Electric elbow prosthesis
9X18	Cable Pull Switch	41099	Electric elbow prosthesis
9X25	Rocker Switch	41099	Electric elbow prosthesis
9X37	Pressure Switch	41099	Electric elbow prosthesis
9X50	Linear Transducer	41099	Electric elbow prosthesis
9X51	4-Step Transducer	41099	Electric elbow prosthesis
9X52	Linear Transducer	41099	Electric elbow prosthesis
9X53	4-Step Transducer	41099	Electric elbow prosthesis

Notice: An asterisk indicates that there are multiple variants available.