

EU Declaration of Conformity

The signatories, who represent the below-mentioned manufacturer,

Manufacturer:

Otto Bock Healthcare Products GmbH
Brehmstraße 16
1110 Wien, Austria
SRN: AT-MF-000002920

herewith declare in sole responsibility that the products listed in Appendix I are in conformity with the relevant provisions of the below-mentioned EU Regulation(s), EU Directive(s) and Common Specification(s):

(EU) 2017/745 Regulation of the European Parliament and of the Council of
5 April 2017 on medical devices

Notified Body: N.A.
Notified Body Address: N.A.
Notified Body Number: N.A.

The conformity is declared based on Article 52(7), Annex II and Annex III of the Regulation (EU) 2017/745.

This declaration is valid for products placed on the market as of the date of this issue.

Vienna, 2023-03-23

Place, Date



Reinhard Wolkerstorfer
Person Responsible for
Regulatory Compliance



Andreas Eichler
Managing Director

Appendix I – Medical Devices (acc. to Regulation (EU) 2017/745)

Please note that all given product numbers are the main product numbers.

Some products are available in variants – this will show as e.g. 12K100N=50

Article Number	Product Name	Classification acc. to (EU) 2017/745 Annex VIII	Basic UDI-DI
10S17	Electric Wrist Rotator	Class I, Rule 1, 13	406441100000000010S17J8
12K100N*	DynamicArm	Class I, Rule 1, 13	40644110000000012K100NQC
12K110N*	DynamicArm Plus	Class I, Rule 1, 13	40644110000000012K110NQH
12K41*	ErgoArm	Class I, Rule 1	406441100000000012K41HB
12K42*	ErgoArm plus	Class I, Rule 1	406441100000000012K42HD
12K44*	ErgoArm Hybrid plus	Class I, Rule 1, 13	406441100000000012K44HH
12K50*	ErgoArm Electronic plus	Class I, Rule 1, 13	406441100000000012K50HC
12K501*	AxonArm Ergo	Class I, Rule 1, 13	40644110000000012K501KN
12V10	Tube Valve for Suction Socket	Class I, Rule 1	406441100000000012V10JP
13E100*	AnalogAdapter	Class I, Rule 1, 13	40644110000000013E100HZ
13E200*	Electrode	Class I, Rule 1, 13	40644110000000013E200J6
13E202*	Suction Socket Electrode	Class I, Rule 1, 13	40644110000000013E202JA
13E205	MyoRotronic	Class I, Rule 1, 13	40644110000000013E205JG
13E400*	Remote Electrode	Class I, Rule 1, 13	40644110000000013E400JG
13E401*	Remote Electrode	Class I, Rule 1, 13	40644110000000013E401JJ
13E500*	AxonMaster	Class I, Rule 1, 13	40644110000000013E500JM
13E520*	Myo Plus TR	Class I, Rule 1, 13	40644110000000013E520JT
17CF2*	Spring Element	Class I, Rule 1, 13	406441100000000017CF2JT
17K01*	C-Brace joint unit	Class I, Rule 1, 13	406441100000000017K01LU
17K01A=SET	Correction adapter set	Class I, Rule 1	40644110000000017K01ASB
1B1-2*	Meridium	Class I, Rule 1, 13	40644110000000001B1-2G4
21A47*	Transhumeral Soft Harness	Class I, Rule 1	406441100000000021A47G9
2R17*	AXON Tube Adapter	Class I, Rule 1, 13	406441100000000002R17J6
2R19*	AXON Tube Adapter	Class I, Rule 1, 13	406441100000000002R19JA
2R20*	AXON Tube Adapter	Class I, Rule 1, 13	406441100000000002R20HT
2R21*	AXON Tube Adapter with Torsion	Class I, Rule 1, 13	406441100000000002R21HV
2R67*	Tube adapter with torsion unit, Ø34 mm	Class I, Rule 1	406441100000000002R67JM
3B1-3*	Genium	Class I, Rule 1, 13	40644110000000003B1-3GU
3B5-3*	Genium X3	Class I, Rule 1, 13	40644110000000003B5-3HG
3C60*	Kenevo	Class I, Rule 1, 13	406441100000000003C60G3
3C88-3*	C-Leg	Class I, Rule 1, 13	40644110000000003C88-3NC
3C98-3*	C-Leg	Class I, Rule 1, 13	40644110000000003C98-3NK
3F1=1	Functional Cosmesis C-Leg	Class I, Rule 1	40644110000000003F1=1K4
3F1=1-N	Functional Cosmesis C-Leg (Knee Part)	Class I, Rule 1	4064411000000003F1=1-NT2
3F1=2	Functional Cosmesis Genium	Class I, Rule 1	40644110000000003F1=2K6
3F1=2-N	Functional Cosmesis Genium (Knee Part)	Class I, Rule 1	4064411000000003F1=2-NT7

Article Number	Product Name	Classification acc. to (EU) 2017/745 Annex VIII	Basic UDI-DI
4E50-2*	Battery Charger for C-Leg	Class I, Rule 1, 13	406441100000000004E50GH
4E50-3*	Battery Charger for C-Leg	Class I, Rule 1, 13	40644110000000004E50-3MJ
4E60*	Inductive Charger	Class I, Rule 1, 13	406441100000000004E60GL
4E70*	Inductive Charger	Class I, Rule 1, 13	406441100000000004E70GP
4E70-1*	Inductive Charger	Class I, Rule 1, 13	40644110000000004E70-1MU
4P862	C-Leg Guard	Class I, Rule 1	40644110000000004P862N5
4P863*	Shield insert	Class I, Rule 1	40644110000000004P863N7
4R110	Lamination anchor for children	Class I, Rule 1	40644110000000004R110LV
4R112*	Sliding Adapter Set	Class I, Rule 1	40644110000000004R112LZ
4R120	DeltaTwist	Class I, Rule 1	40644110000000004R120LY
4R121*	DeltaTwist	Class I, Rule 1	40644110000000004R121M2
4R39	Torsion Adapter	Class I, Rule 1	40644110000000004R39JW
4R40	Torsion Adapter	Class I, Rule 1	40644110000000004R40JF
4R57*	Rotation Adapter	Class I, Rule 1	40644110000000004R57JY
4R57=WR*	Rotation adapter	Class I, Rule 1	406441100000004R57=WR6K
4R85	Torsion Adapter	Class I, Rule 1	40644110000000004R85K5
4R86	Torsion Adapter	Class I, Rule 1	40644110000000004R86K7
4X1=V1.10	X-Soft 1.10	Class I, Rule 1, 13	4064411000004X1=V1.10QP
4X154=V1.4	M-Soft 1.4	Class I, Rule 1, 13	406441100004X154=V1.4VF
4X160*	C-Leg Protector	Class I, Rule 1	40644110000000004X160NN
4X180=V2.8	C-Soft 2.8	Class I, Rule 1, 13	406441100004X180=V2.8VT
4X193-1*	Genium X3 Protective Cover	Class I, Rule 1	406441100000004X193-1YK
4X440=V1.10	C-Soft Plus 1.10	Class I, Rule 1, 13	406441100004X440=V1.8VB
4X440=V1.8	C-Soft Plus 1.8	Class I, Rule 1, 13	406441100004X440=V1.8VB
4X441-V2=*	Cockpit	Class I, Rule 1, 13	4064411000004X441-V29K
4X445=V1.4	K-Soft 1.4	Class I, Rule 1, 13	406441100004X445=V1.4X4
4X445=V1.6	K-Soft 1.6	Class I, Rule 1, 13	406441100004X445=V1.6X8
4X840	Kenevo Protective Cover	Class I, Rule 1	40644110000000004X840PK
4X860*	C-Leg Protective Cover (w/o shield)	Class I, Rule 1	40644110000000004X860PR
4X900*	Genium X3 Protective Cover	Class I, Rule 1	40644110000000004X900PC
560X12=V1.4	bebalance+ 1.4	Class I, Rule 1, 13	4064411000560X12=V1.4TP
560X12=V1.6	bebalance+ 1.6	Class I, Rule 1, 13	4064411000560X12=V1.6TT
560X17-*=V1.2	C-Brace Setup	Class I, Rule 1, 13	40644110560X17-*=V1.2AE
560X18-*=V1.2	Myo Plus	Class I, Rule 1, 13	40644110560X18-*=V1.2AZ
560X23-V1=*	Kenevo A-B-C	Class I, Rule 1, 13	406441100000560X23-V17J
560X3=V1.0	MyolinoSoft	Class I, Rule 1, 13	40644110000560X3=V1.0PF
560X500=V2.2	AxonSoft 2.2	Class I, Rule 1, 13	406441100560X500=V2.23M
5A60=*	Varos	Class I, Rule 1	40644110000000005A60G7
60X6	MyolinoLink	Class I, Rule 1, 13	406441100000000060X6HD
60X7	BionicLink	Class I, Rule 1, 13	406441100000000060X7HF
646C42=V1.6	ElbowSoft 1.6	Class I, Rule 1, 13	4064411000646C42=V1.6LE
646C52=V1.2	PAULA 1.2	Class I, Rule 1, 13	4064411000646C52=V1.2LP
646C57=V1.4	ElbowSoft TMR 1.4	Class I, Rule 1, 13	4064411000646C57=V1.4NU
757B20*	EnergyPack	Class I, Rule 1, 13	406441100000000757B20LY
757B21*	EnergyPack	Class I, Rule 1, 13	406441100000000757B21M2

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757B35=0*	MyoEnergy Integral	Class I, Rule 1, 13	40644110000000757B35=0W7
757B35=1	MyoEnergy Integral	Class I, Rule 1, 13	40644110000000757B35=1W9
757B35=3	MyoEnergy Integral	Class I, Rule 1, 13	40644110000000757B35=3WD
757B35=4*	MyoEnergy Integral	Class I, Rule 1, 13	4064411000000000757B35MD
757B35=5*	MyoEnergy Integral	Class I, Rule 1, 13	40644110000000757B35=5WH
757B501*	AxonEnergy Integral	Class I, Rule 1, 13	406441100000000757B501QR
757L35*	MyoCharge Integral	Class I, Rule 1, 13	4064411000000000757L35NX
757L500*	AxonCharge Integral	Class I, Rule 1, 13	406441100000000757L500SV
757M11=2	MyoBoy Light	Class I, Rule 1, 13	4064411000000000757M11NN
757M20*	Myo Cuff	Class I, Rule 1, 13	4064411000000000757M20NP
8E3*=9*	System Electric Greifer DMC VariPlus	Class I, Rule 1, 13	40644110000000008E3*=9PN
8E**=6*	System Electric Hand DMC plus	Class I, Rule 1, 13	40644110000000008E38=6RN 40644110000000008E39=6RT
8E**=7*	System Electric Hand Digital Twin	Class I, Rule 1, 13	40644110000000008E38=7RQ 40644110000000008E39=7RV
8E**=8*	SensorHand Speed / SensorHand Speed Flex	Class I, Rule 1, 13	40644110000000008E38=8RS 40644110000000008E39=8RX 40644110000000008E43=8R8
8E**=9*	MyoHand VariPlus Speed	Class I, Rule 1, 13	40644110000000008E38=9RU 40644110000000008E39=9RZ 40644110000000008E41=9QY
8E44=6*	Transcarpal Hand DMC plus	Class I, Rule 1, 13	40644110000000008E44=6R9
8E500*	Michelangelo Hand	Class I, Rule 1, 13	406441100000000008E500KX
8E51*	Electric Hand 2000	Class I, Rule 1, 13	4064411000000000008E51HF
8E550*	Michelangelo Hand Transcarpal	Class I, Rule 1, 13	406441100000000008E550LE
8E600*	AxonHook	Class I, Rule 1, 13	406441100000000008E600L4
8E70*	bebionic Hand EQD	Class I, Rule 1, 13	406441100000000008E70HK
8E71*	bebionic Hand Short Wrist	Class I, Rule 1, 13	406441100000000008E71HM
8E72*	bebionic Hand Flex	Class I, Rule 1, 13	406441100000000008E72HP
8K50*	MyoFacil	Class I, Rule 1, 13	406441100000000008K50JB
8R1*	Endoskeletal Adapter	Class I, Rule 1	4064411000000000008R1GF
99B120*	Functional Stocking	Class I, Rule 1	406441100000000099B120NU
9E420*	7in1 Controller	Class I, Rule 1, 13	406441100000000009E420LB
9S501*	AxonRotation Adapter	Class I, Rule 1, 13	406441100000000009S501PE
9S503*	AxonRotation	Class I, Rule 1, 13	406441100000000009S503PJ
9X14	Harness Pull Switch	Class I, Rule 1, 13	4064411000000000009X14LF
9X18	Cable Pull Switch	Class I, Rule 1, 13	4064411000000000009X18LP
9X25	Rocker Switch	Class I, Rule 1, 13	4064411000000000009X25LL
9X37	Pressure Switch	Class I, Rule 1, 13	4064411000000000009X37LT
9X50	Linear Transducer	Class I, Rule 1, 13	4064411000000000009X50LK
9X51	4-Step Transducer	Class I, Rule 1, 13	4064411000000000009X51LM
9X52	Linear Transducer	Class I, Rule 1, 13	4064411000000000009X52LP
9X53	4-Step Transducer	Class I, Rule 1, 13	4064411000000000009X53LR