

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, 2024-06-27

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 be shown as e.g. 12K100N=50

| Article Number | Product Name | Classification acc. to (EU) 2017/745 Annex VIII | Device Type | Basic UDI-DI |
|----------------|--|---|---------------------|--------------------------|
| 10S17 | Electric Wrist Rotator | Medical Device | Class I, Rule 1, 13 | 406441100000000010S17J8 |
| 12K100N* | DynamicArm | Medical Device | Class I, Rule 1, 13 | 40644110000000012K100NQC |
| 12K110N* | DynamicArm Plus | Medical Device | Class I, Rule 1, 13 | 40644110000000012K110NQH |
| 12K41* | ErgoArm | Medical Device | Class I, Rule 1 | 406441100000000012K41HB |
| 12K42* | ErgoArm plus | Medical Device | Class I, Rule 1 | 406441100000000012K42HD |
| 12K44* | ErgoArm Hybrid plus | Medical Device | Class I, Rule 1, 13 | 406441100000000012K44HH |
| 12K50* | ErgoArm Electronic plus | Medical Device | Class I, Rule 1, 13 | 406441100000000012K50HC |
| 12K501* | AxonArm Ergo | Medical Device | Class I, Rule 1, 13 | 40644110000000012K501KN |
| 12V10 | Tube Valve for Suction Socket | Accessory for a medical device | Class I, Rule 1 | 406441100000000012V10JP |
| 13E100* | AnalogAdapter | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E100HZ |
| 13E200* | Electrode | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E200J6 |
| 13E202* | Suction Socket Electrode | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E202JA |
| 13E205 | MyoRotronic | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E205JG |
| 13E400* | Remote Electrode | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E400JG |
| 13E401* | Remote Electrode | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E401JJ |
| 13E500* | AxonMaster | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E500JM |
| 13E520* | Myo Plus TR | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000013E520JT |
| 17K01* | C-Brace joint unit | Medical Device | Class I, Rule 1, 13 | 406441100000000017K01LU |
| 17K01A=SET | Correction adapter set | Accessory for a medical device | Class I, Rule 1 | 40644110000000017K01ASB |
| 1B1-2* | Meridium | Medical Device | Class I, Rule 1, 13 | 40644110000000001B1-2G4 |
| 21A47* | Transhumeral Soft Harness | Accessory for a medical device | Class I, Rule 1 | 406441100000000021A47G9 |
| 2R17* | AXON Tube Adapter | Medical Device | Class I, Rule 1, 13 | 40644110000000002R17J6 |
| 2R19* | AXON Tube Adapter | Medical Device | Class I, Rule 1, 13 | 40644110000000002R19JA |
| 2R20* | AXON Tube Adapter | Medical Device | Class I, Rule 1, 13 | 40644110000000002R20HT |
| 2R21* | AXON Tube Adapter with Torsion | Medical Device | Class I, Rule 1, 13 | 40644110000000002R21HV |
| 2R67* | Tube adapter with torsion unit, Ø34 mm | Medical Device | Class I, Rule 1 | 40644110000000002R67JM |

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|----------------|--|---|---------------------|---------------------------|
| 2R68=* | AXON Tube Adapter | Medical Device | Class I, Rule 1, 13 | 406441100000000002R68JP |
| 2R69=* | AXON Tube Adapter with Torsion | Medical Device | Class I, Rule 1, 13 | 406441100000000002R69JR |
| 2R81* | C-Leg Tube Adapter with Torsion Unit | Medical Device | Class I, Rule 1, 13 | 406441100000000002R81JF |
| 2R82* | C-leg Tube Adapter | Medical Device | Class I, Rule 1, 13 | 406441100000000002R82JH |
| 3B1-3* | Genium | Medical Device | Class I, Rule 1, 13 | 406441100000000003B1-3GU |
| 3B5-3* | Genium X3 | Medical Device | Class I, Rule 1, 13 | 406441100000000003B5-3HG |
| 3B5-4=* | Genium X4 | Medical Device | Class I, Rule 1, 13 | 406441100000000003B5-4HJ |
| 3C60* | Kenevo | Medical Device | Class I, Rule 1, 13 | 406441100000000003C60G3 |
| 3C88-3* | C-Leg | Medical Device | Class I, Rule 1, 13 | 406441100000000003C88-3NC |
| 3C98-3* | C-Leg | Medical Device | Class I, Rule 1, 13 | 406441100000000003C98-3NK |
| 3D13=* | Thigh kit/Magnetic closure | Accessory for a medical device | Class I, Rule 1 | 406441100000000003D13FX |
| 3F1=1 | Functional Cosmesis C-Leg | Accessory for a medical device | Class I, Rule 1 | 406441100000000003F1=1K4 |
| 3F1=1-N | Functional Cosmesis C-Leg (Knee Part) | Accessory for a medical device | Class I, Rule 1 | 4064411000000003F1=1-NT2 |
| 3F1=2 | Functional Cosmesis Genium | Accessory for a medical device | Class I, Rule 1 | 406441100000000003F1=2K6 |
| 3F1=2-N | Functional Cosmesis Genium (Knee Part) | Accessory for a medical device | Class I, Rule 1 | 4064411000000003F1=2-NT7 |
| 3F2=* | Functional cosmesis Genium X4 | Accessory for a medical device | Class I, Rule 1 | 406441100000000003F2EL |
| 4E50-2* | Battery Charger for C-Leg | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000004E50GH |
| 4E50-3* | Battery Charger for C-Leg | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000004E50-3MJ |
| 4E60* | Inductive Charger | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000004E60GL |
| 4E70* | Inductive Charger | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000004E70GP |
| 4E70-1* | Inductive Charger | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000004E70-1MU |
| 4P100=* | Genium X4 Protective cover, short | Accessory for a medical device | Class I, Rule 1 | 406441100000000004P100LC |
| 4P110=* | Genium X4 Protective cover, long | Accessory for a medical device | Class I, Rule 1 | 406441100000000004P110LF |
| 4P112=* | Functional knee part | Accessory for a medical device | Class I, Rule 1 | 406441100000000004P112LK |
| 4P862 | C-Leg Guard | Accessory for a medical device | Class I, Rule 1 | 406441100000000004P862N5 |
| 4P863* | Shield insert | Accessory for a medical device | Class I, Rule 1 | 406441100000000004P863N7 |
| 4R110 | Lamination anchor for children | Medical Device | Class I, Rule 1 | 406441100000000004R110LV |
| 4R112* | Sliding Adapter Set | Medical Device | Class I, Rule 1 | 406441100000000004R112LZ |
| 4R120 | DeltaTwist | Medical Device | Class I, Rule 1 | 406441100000000004R120LY |
| 4R121* | DeltaTwist | Medical Device | Class I, Rule 1 | 406441100000000004R121M2 |
| 4R39 | Torsion Adapter | Medical Device | Class I, Rule 1 | 406441100000000004R39JW |

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| 4R40 | Torsion Adapter | Medical Device | Class I, Rule 1 | 40644110000000004R40JF |
| 4R57* | Rotation Adapter | Medical Device | Class I, Rule 1 | 40644110000000004R57JY |
| 4R57=WR* | Rotation adapter | Medical Device | Class I, Rule 1 | 406441100000004R57=WR6K |
| 4R85 | Torsion Adapter | Medical Device | Class I, Rule 1 | 40644110000000004R85K5 |
| 4R86 | Torsion Adapter | Medical Device | Class I, Rule 1 | 40644110000000004R86K7 |
| 4X1=V1.10 | X-Soft 1.10 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X1=V1.10QP |
| 4X154=V1.4 | M-Soft 1.4 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X154=V1.4VF |
| 4X160* | C-Leg Protector | Accessory for a medical device | Class I, Rule 1 | 40644110000000004X160NN |
| 4X180=V2.8 | C-Soft 2.8 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X180=V2.8VT |
| 4X193-1* | Genium X3 Protective Cover | Accessory for a medical device | Class I, Rule 1 | 406441100000004X193-1YK |
| 4X440=V1.10 | C-Soft Plus 1.10 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X440=V1.8VB |
| 4X440=V1.8 | C-Soft Plus 1.8 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X440=V1.8VB |
| 4X441-V2=* | Cockpit | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000004X441-V29K |
| 4X445=V1.4 | K-Soft 1.4 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X445=V1.4X4 |
| 4X445=V1.6 | K-Soft 1.6 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000004X445=V1.6X8 |
| 4X840 | Kenevo Protective Cover | Accessory for a medical device | Class I, Rule 1 | 40644110000000004X840PK |
| 4X860* | C-Leg Protective Cover (w/o shield) | Accessory for a medical device | Class I, Rule 1 | 40644110000000004X860PR |
| 4X900* | Genium X3 Protective Cover | Accessory for a medical device | Class I, Rule 1 | 40644110000000004X900PC |
| 560X12=V1.4 | bebalance+ 1.4 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000560X12=V1.4TP |
| 560X12=V1.6 | bebalance+ 1.6 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000560X12=V1.6TT |
| 560X17-*=V1.2 | C-Brace Setup | Accessory for a medical device | Class I, Rule 1, 13 | 40644110560X17-*=V1.2AE |
| 560X18-1=* | Myo Plus | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000560X18-1YU |
| 560X23-V1=* | Kenevo A-B-C | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000560X23-V17J |
| 560X29-1* | connectgo.pro | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000560X29-1Z8 |
| 560X3=V1.0 | MyolinoSoft | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000560X3=V1.0PF |
| 560X500=V2.2 | AxonSoft 2.2 | Accessory for a medical device | Class I, Rule 1, 13 | 406441100560X500=V2.23M |
| 5A60=* | Varos | Medical Device | Class I, Rule 1 | 406441100000000005A60G7 |
| 60X3* | BionicLink | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000060X3H7 |
| 60X6 | MyolinoLink | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000060X6HD |
| 60X7 | BionicLink | Accessory for a medical device | Class I, Rule 1, 13 | 406441100000000060X7HF |
| 646C42=V1.6 | ElbowSoft 1.6 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000646C42=V1.6LE |

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|----------------|--------------------------------------|---|---------------------|--|
| 646C52=V1.2 | PAULA 1.2 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000646C52=V1.2LP |
| 646C57=V1.4 | ElbowSoft TMR 1.4 | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000646C57=V1.4NU |
| 757B20* | EnergyPack | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757B20LY |
| 757B21* | EnergyPack | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757B21M2 |
| 757B35=0* | MyoEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000757B35=0W7 |
| 757B35=1 | MyoEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000757B35=1W9 |
| 757B35=3 | MyoEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000757B35=3WD |
| 757B35=4* | MyoEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757B35MD |
| 757B35=5* | MyoEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000757B35=5WH |
| 757B501* | AxonEnergy Integral | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757B501QR |
| 757L35* | MyoCharge Integral | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757L35NX |
| 757L47=* | USB Adapter for charging | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757L47P6 |
| 757L500* | AxonCharge Integral | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757L500SV |
| 757M11=2 | MyoBoy Light | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757M11NN |
| 757M20* | Myo Cuff | Accessory for a medical device | Class I, Rule 1, 13 | 40644110000000757M20NP |
| 8E3*=9* | System Electric Greifer DMC VariPlus | Medical Device | Class I, Rule 1, 13 | 406441100000008E3*=9PN |
| 8E**=6* | System Electric Hand DMC plus | Medical Device | Class I, Rule 1, 13 | 406441100000008E38=6RN 406441100000008E39=6RT |
| 8E**=7* | System Electric Hand Digital Twin | Medical Device | Class I, Rule 1, 13 | 406441100000008E38=7RQ 406441100000008E39=7RV |
| 8E**=8* | SensorHand Speed | Medical Device | Class I, Rule 1, 13 | 406441100000008E38=8RS 406441100000008E39=8RX 406441100000008E43=8R8 |
| 8E**=9* | MyoHand VariPlus Speed | Medical Device | Class I, Rule 1, 13 | 406441100000008E38=9RU 406441100000008E39=9RZ 406441100000008E41=9QY |
| 8E44=6* | Transcarpal Hand DMC plus | Medical Device | Class I, Rule 1, 13 | 406441100000008E44=6R9 |
| 8E500* | Michelangelo Hand | Medical Device | Class I, Rule 1, 13 | 406441100000008E500KX |
| 8E51* | Electric Hand 2000 | Medical Device | Class I, Rule 1, 13 | 40644110000000008E51HF |
| 8E550* | Michelangelo Hand Transcarpal | Medical Device | Class I, Rule 1, 13 | 40644110000000008E550LE |
| 8E600* | AxonHook | Medical Device | Class I, Rule 1, 13 | 40644110000000008E600L4 |
| 8E70* | bebionic Hand EQD | Medical Device | Class I, Rule 1, 13 | 40644110000000008E70HK |
| 8E71* | bebionic Hand Short Wrist | Medical Device | Class I, Rule 1, 13 | 40644110000000008E71HM |
| 8E72* | bebionic Hand Flex | Medical Device | Class I, Rule 1, 13 | 40644110000000008E72HP |
| 8K50* | MyoFacil | Medical Device | Class I, Rule 1, 13 | 40644110000000008K50JB |
| 8R1* | Endoskeletal Adapter | Medical Device | Class I, Rule 1 | 40644110000000008R1GF |

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|----------------|----------------------|---|---------------------|-------------------------|
| 9002M=03 | Fixture | Accessory for a medical device | Class I, Rule 1 | 40644110000009002M=03SE |
| 99B120* | Functional Stocking | Accessory for a medical device | Class I, Rule 1 | 40644110000000099B120NU |
| 99B122=* | Functional stocking | Accessory for a medical device | Class I, Rule 1 | 40644110000000099B122NY |
| 9E420* | 7in1 Controller | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009E420LB |
| 9S501* | AxonRotation Adapter | Medical Device | Class I, Rule 1, 13 | 4064411000000009S501PE |
| 9S503* | AxonRotation | Medical Device | Class I, Rule 1, 13 | 4064411000000009S503PJ |
| 9X14 | Harness Pull Switch | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X14LF |
| 9X18 | Cable Pull Switch | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X18LP |
| 9X25 | Rocker Switch | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X25LL |
| 9X37 | Pressure Switch | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X37LT |
| 9X50 | Linear Transducer | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X50LK |
| 9X51 | 4-Step Transducer | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X51LM |
| 9X52 | Linear Transducer | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X52LP |
| 9X53 | 4-Step Transducer | Accessory for a medical device | Class I, Rule 1, 13 | 4064411000000009X53LR |