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EU-Konformitätserklärung
EU Declaration of Conformity

Der Unterzeichner, der den nachstehenden Hersteller vertritt,
The signatory, who represents the below-mentioned manufacturer,

Hersteller / *Manufacturer*

Otto Bock Healthcare Plc
32 Parsonage Road
Englefield Green
Egham
Surrey, TW20 0LD
United Kingdom

SRN: N/A

erklärt hiermit in alleiniger Verantwortung, dass das Produkt
herewith declares under his sole responsibility that the product

Produkt / *Product*

Orthotic Ankle Joints

Bezeichnung	Name
Risikoklasse I	Risk class I
gemäß Verordnung (EU) 2017/745	according to Regulation (EU) 2017/745
Basis-UDI-DI (GMN):	Basic UDI-DI (GMN):

in folgenden Varianten
in the following variants

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Varianten / *Variants*

Article number	Variants	Description Orthotic	MDR Risk Class	GMDN No.	Basic UDI-DI
17A1=14-A	17A1=*	Flat Spur	I	30999	406440700000000017A1N3
17A1=14-CS			I	30999	406440700000000017A1N3
17A1=13-CS			I	30999	406440700000000017A1N3
17A1=13-A			I	30999	406440700000000017A1N3
17A2=16-A	17A2=*	Leg Iron	I	30999	406440700000000017A2N5
17A3=16-A	17A3=*		I	30999	406440700000000017A3N7
17A4=13-A	17A4=*		I	30999	406440700000000017A4N9
17A5=13-A	17A5=*		I	30999	406440700000000017ALZ
17A6=13-CS	17A6=*	Medium Leg Iron	I	30999	406440700000000017A6ND
17A6=11-CS			I	30999	406440700000000017A6ND
17A6=9-CS			I	30999	406440700000000017A6ND
17AD1=120	17AD1=*	Dual Function Ankle Joint	I	30999	40644070000000017AD1RE
17AD1=93			I	30999	40644070000000017AD1RE
17AD18=13-CS	17AD18=*	Adult Bicaal Ankle Joint	I	30999	4064407000000017AD18V3
17AD18=16-A			I	30999	4064407000000017AD18V3
17AD19=13-CS	17AD19=*	Childs Bicaal Ankle Joint	I	30999	4064407000000017AD19V5
17AD19=13-A			I	30999	4064407000000017AD19V5
17AF2=77	17AF2=*	Active Contour Ankle Joint	I	30999	40644070000000017AF2RN
17AF2=63			I	30999	40644070000000017AF2RN
17AS5=L-13-CS	17AS5=*	Concealed Spring Ankle Joint	I	30999	406440700000000017AS5T3
17AS5=R-13-CS			I	30999	406440700000000017AS5T3
17AS5=L-16-A			I	30999	406440700000000017AS5T3
17AS5=R-16-A			I	30999	406440700000000017AS5T3
17AS4=L-13-CS	17AS4=*		I	30999	406440700000000017AS4SZ
17AS4=R-13-CS			I	30999	406440700000000017AS4SZ
17AS4=13-A			I	30999	406440700000000017AS4SZ
17SF1=1-CS	17SF1=*	Round Socket	I	30999	40644070000000017SF1UE
17SF1=2-CS			I	30999	40644070000000017SF1UE
17SF1=3-CS			I	30999	40644070000000017SF1UE
17SF2=1-CS	17SF2=*	Box Socket	I	30999	40644070000000017SF2UG
17SF2=2-CS			I	30999	40644070000000017SF2UG

mit den Bestimmungen der nachstehenden EU-Verordnung(en), EU-Richtlinie(n) und Gemeinsame Spezifikation(en) übereinstimmt.
is in conformity with the relevant provisions of below-mentioned EC Regulation(s), EC Directive(s) and Common Specification(s).

2017/745 EU Verordnung des Europäischen Parlaments und des Rates über Medizinprodukte
Regulation of the European Parliament and of the Council on medical devices
Gemeinsame Spezifikation(en) / Common specification(s): N/A

Die Konformität wird erklärt nach Artikel 52(7), Anhang II und III der Verordnung (EU) 2017/745.
The conformity is declared based on Article 52(7), Annex II and III of the Regulation (EU) 2017/745.

Unitd Kindom, 2020-06-15

Ort, Datum / *Place, Date*

Philp Yates
Geschäftsführer
Managing Director

Graeme.Goody
Für die Einhaltung der Regulierungsvorschriften verantwortliche Person
Person Responsible for Regulatory Compliance

Aufzeichnungshistorie/ *Document history*

Effective date	Reason for change	Comments
2020-06-15	Initial version	