

MANUFACTURER'S DECLARATION OF CONFORMITY

UNITED KINGDOM "THE RADIO EQUIPMENT REGULATION 2017" DECLARATION OF CONFORMITY

This declaration of conformity is made under Schedule II of the Radio Equipment Regulations 2017.

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

The signatories, who represent the manufacturer, herewith declare in sole responsibility that the products listed in the attached schedule are in conformity with the relevant provisions of the below-mentioned UK Regulation:

UK Statutory Instruments 2017 No. 1206: The Radio Equipment Regulations 2017

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

This declaration applies to all products covered by the above definition and that are manufactured after the date of issue of this declaration as specified in their respective manufacturing documents.

Vienna, 2023-07-07

Place, Date



Reinhard Wolkerstorfer
Head of Regulatory Affairs



Andreas Eichler
Managing Director

Article Number	Product Name
12K100N*	DynamicArm
12K110N*	DynamicArm Plus
13E500*	AxonMaster
13E520*	Myo Plus TR
17K01*	C-Brace joint unit
1B1-2*	Meridium
3B1-3*	Genium
3B5-3*	Genium X3
3C60*	Kenevo
3C88-3*	C-Leg
3C98-3*	C-Leg
4E70-1	Inductive Charger
60X6	MyolinoLink
60X7	BionicLink
757M20*	Myo Cuff
8E70*	bebionic Hand EQD
8E71*	bebionic Hand Short Wrist
8E72*	bebionic Hand Flex
60X5*	BionicLink PC

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