CE Declaration of Conformity

Name of Manufacturer: **Address of Manufacturer:**	Orthobroker bv Ter Stratenweg 11, B-2520 Ranst Belgium – tel. +32 3385 1075 info@orthobroker.com
Single Registration number (SRN)	BE-MF-000000331
EMDN code	Y06

We herewith declare under its sole responsibility that the below-mentioned product(s) meet the requirements of:

- EN ISO 13485:2016: Medical devices – Quality management systems – Requirements for regulatory purposes
- Medical Device Regulation 2017/745

and that all documentation to support this Declaration of Conformity is available for review and shall be kept on file at Orthobroker bv.

Classification:	Class I Rule 1: non-sterile, non-measuring
Conformity assessment route:	MDR 2017/745, Annex IX
Notified Body:	DQS Medizinprodukte GmbH Identification number: 0297
EN ISO 13485:2016 ISO Certificate number:	524389 MP2016
Notification number at Belgian Competent authority (FAMHP) **Date CE Marking affixed:**	BE/CA01/1-06283 13 August 2010
Place and Date::	Ranst, Belgium - 21/11/2022
Signature:	
Name: **Position:**	Patrick Garmyn Director

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Device code	Trade name (BraceID)	Basic UDI-DI	Intended use
11-0040	Embrace Wrist	5404020402wristhandZ6	The upper extremity wrist and hand orthoses are external passive supports used after injuries or chronic instabilities.
11-0041	Embrace Wrist & Thumb	5404020402wristhandZ6	
11-0042	Thumb Spica Splint	5404020402wristhandZ6	
11-0043	D-Ring Wrist Brace	5404020402wristhandZ6	
11-0045	LONG D-Ring Wrist Brace	5404020402wristhandZ6	
11-0046xT	Stack Finger Splint-Transparent	5404020402wristhandZ6	
11-0046xB	Stack Finger Splint-Beige	5404020402wristhandZ6	
11-0047	D-Ring Wrist & Thumb Brace	5404020402wristhandZ6	
11-0052	Open D-Ring Wrist Brace	5404020402wristhandZ6	

Used Common Specifications:

"No Common Specifications are available for the products as indicated in this Declaration of Conformity".

Used harmonized standards:

EN ISO 13485: 2016/ A11:2021
EN ISO14971:2019:A11:2021
EN ISO 10993-10:2023
EN ISO 15223-1: 2021
EN ISO 12100:2010
EN ISO 11553-1:2020/A11:2020
EN ISO 13849-1:2015
EN ISO 19353:2019
EN ISO 13850:2020

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