



Declaration of Conformity

Manufacturer: COBI Rehab ApS
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The undersigned declares that the product named and listed on this certificate is constructed and manufactured in accordance with the essential requirements of The Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 relating to Medical Devices Class 1.

Risk analysis has been executed in accordance with EN ISO 14971:2012 Medical devices
- Application of risk management to medical devices.

The devices comply to the following standards:

EN 12182: 2012 – 16.2 Static forces
BS EN ISO 11334-1 (Elbow Crutch)

General product name:	Bariatric Elbow Crutch, Bariatric Cane, Bariatric 4-point cane
Item No.:	0200-000-000, 0201-000-000, 0205-000-000C, 0205-000-000LC, 0205-000-000RC
Risk Class:	I
Intended use:	Assistive devices for persons with special needs
Basic UDI-DI:	5740000100010MV
SRN:	DK-MF-000001370

Kastrup, 17-02-2021

Claus Nymark, Director