



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:

BS EN 597-1:1995
BS EN 597-2:1995
BS 6807:2006 Wooden Crib 5
BS 7177:2008
BS 7175:1989-3 Wooden Crib 5

General product name:	Comfort Cushion, Viscocomfort Cushion
Item No.:	0230-055-045, 0230-061-045, 0230-066-045, 0230-072-045 0230-082-045, 0233-056-050, 0233-061-050, 0233-066-050, 0233-071-050, 0233-076-050, 0233-081-050, 0233-091-050, 0233-096-050, 0233-100-050
Risk Class:	I
Intended use:	Assistive devices for persons with special needs
Basic UDI-DI:	5740000100011MX
SRN:	DK-MF-000001370

Kastrup, 17-02-2021

Claus Nymark, Director