# EU Declaration of Conformity

This document applies to the following products:

| Model | Model Name | Basic UDI-DI | Intended Purpose |
|---|---|---|---|
| 8016-50** | Rotobed®SafeSleep | 5745000385SafeSleep6N | Redistribution of the body pressure to reduce surface pressure towards the body and thereby reduce the risk for pressure sore and other pressure related problems. |
| 8018-50** | Rotobed®BariaSleep | 5745000385BariaSleep8X | |
| 8019-50** | Rotobed®ErgoSleep | 5745000385ErgoSleepBA | |
| 8015-50" | RotoBed®ROHO®Dry Flotation | 5745000385RoHoA8 | |
| 8017-10** | RotoBed®AirSleep | 5745000385AirSleep4L | |

Manufacturer:

RotoBed®, Storegade 44, DK-6640 Lunderskov, Denmark
**SRN: DK-MF-**
GS1 Company prefix: 5745000385

Device classification: Class I.
The produet is in conformity with the provisions ofthe REGULATION (EU) 2017/745 produet classification 1.

Conformity assessment route: MOR (EU) 2017/745, Annex IX chapter 1

This EU declaration of conformity is issued under the sole responsibility of RotoBed® ApS, the manufacturer of the below listed CE marked medical devices. The requirements specified in EU Regulation 2017/7 45 (MOR) medical devices have been fulfilled in relation to the listed device groups.

The declared medical devices comply where appropriate, with the foliowing European standards:

DS/EN Iso 20342-1:2019, DS/EN 12182:2012, DS/EN ISO 14971:2012, DS/EN ISO 14971:2019, DS/EN ISO 15223-1:2016, DS/EN 1041+A1:2013, DS/EN 62366:2015, DS/EN ISO 10993-1:2009, DS/EN ISO 10993-10:2013, DS/EN ISO 14155:20l2, M OD 93/42/EC: Medical Device Directive - amended by 2007/47 /EC, MOR 745/2017: Medical Device Regulation -valid from May 26th, 2021, BEK 1263 of 15/12/2008, MEDDEV guideline 2.12.2: rev, MEDDEV guideline 2.4.1: rev 9, MEDDEV guideline 2.7.1: rev 4.

Signed: 03-07-2025 In Lunderskov, Denmark

Martin Riis Holm, CEO