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	

Manufacturer:

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

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

Conformity assessment route: MDR (EU) 2017/745, Annex IX chapt. 1

This EU declaration of conformity is issued under the sole responsibility of Safe4Care ApS, the manufacturer of the below listed CE marked medical devices. The requirements specified in EU Regulation 2017/7 45 (MDR) medical devices have been fulfilled in relation to the listed device groups.

The declared medical devices comply where appropriate, with the following 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 14155:2012, MDD 93/42/EC: Medical Device Directive – amended by 2007/47/EC, MDR 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: 09-10-2024 In Lunderskov, Denmark

Anne Dorthe Elsborg