

EU-declaration of conformity

As manufacturer
ROHO, Inc.
1501 South 74th St.
Belleville, IL 62223 U.S.A.

declares under the sole responsibility that below specified product is in conformity with the

Regulation (EU) 2017/745
on medical devices (MDR)

ROHO, Inc. is a subsidiary of Permobil, Inc.

Trade Names: **THE ADAPTOR® PAD, ROHO® Toilet Seat Cushion, ROHO® Shower/Commode Cushion**

General Descriptions: Neoprene Special Application Cushion
Intended Use: THE ADAPTOR® PAD (THE ADAPTOR) is an air-filled, cellular-design, neoprene surface intended for cushioning and shock absorption needs and reduction of friction on surfaces such as a wheelchair frame, headrest, armrest or footrest to provide skin/soft tissue protection. There is no weight limit.

Intended Use: The ROHO® Toilet Seat Cushion is an adjustable, air-filled, cellular-design, neoprene surface intended for short-term cushioning needs on toilets and portable bedside commodes. There is no weight limit.

Intended Use: The ROHO® Shower/Commode Cushion (Shower/Commode Cushion) is an adjustable, air-filled, cellular-design, support surface that utilizes DRY FLOATATION® technology and is intended for short-term cushioning needs on bedside commodes and shower chairs to provide skin/soft tissue protection. There is no weight limit.

The manufacturer's internal article number(s) is/are:

Cushion
ADAPTOR

SEATTOILET

SEATCMD88LP
SEATCMD89LP
SEATCMD99LP
SEATCMD910LP
SEATCMD1010LP

Basic UDI-DI: Cushion: 613732NSCWE

Manufacturer SRN: US-MF-000018363

Authorized representative: MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

Authorized representative SRN: DE-AR-000005430

Product class: Class I (according to Annex VIII Chapter III, rule 1)

Conformity procedure used: EU declaration of conformity referred to in Article 19 after drawing up the technical documentation set out in Annexes II and III.

Standards: Conformity to the general safety and performance requirements have been demonstrated by using the following standards:
EN 12182:2012
ISO 14971:2019
EN ISO 13485:2016
EN ISO 10993-1:2020
EN 1021-1:2014
EN 1021-2:2014
ISO 13732-1:2008
EN ISO 15223-1:2021
ISO 16840-6:2015

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Place and date: Belleville, Illinois, USA
2024-10-21

On behalf of ROHO, Inc.



Steven Louer
Sr Manager of Quality/Regulatory Compliance