

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 Name: ROHO® DRY FLOATATION® Mattress Overlay System, ROHO® DRY FLOATATION® Bariatric Mattress Overlay System

General Description: Mattress Overlay System, Bariatric Mattress Overlay System

Intended Use: (Mattress) The ROHO DRY FLOATATION Mattress Overlay System (Standard Overlay) and the ROHO DRY FLOATATION Bariatric Mattress Overlay System (Bariatric Overlay) are non-powered, air-filled, adjustable, zoned, reactive, full support surfaces that are intended to conform to an individual's shape to provide skin/soft tissue and deep tissue injury protection and an environment to facilitate wound healing. ROHO mattress overlays must be used on top of standard hospital, nursing home, home care or consumer mattresses. There is no weight limit for the Standard Overlay or Bariatric Overlay, yet they must be properly sized to the bed mattress, and areas of the individual that require skin/soft tissue protection must be supported by the Standard Overlay or Bariatric Overlay.

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

Mattress

BARI39SYSC
BARI42SYSC
BARI48SYSC
BARI54SYSC
BARI60SYSC
BARIMTO

MATTSECT
MATTSECT1610
MATTSECT1710
MATTSECTMTO
MATTSYS
MATTSYSC
MATTSECTDEMO

Basic UDI-DI: Mattress: 613732NMOWL

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 12952-1:2010
EN ISO 12952-2:2010
EN ISO 15223-1:2021

Original drawn up: 2020-10-15

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

On behalf of ROHO, Inc.



Steven Louer
Senior Manager QA/RC