



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(s): ROHO® Hybrid Select Cushion

General Description: Hybrid Select Cushion

Intended Use: The ROHO Hybrid Select Cushion (Hybrid Select) is an adjustable, air-filled, wheelchair support surface combining a ROHO DRY FLOATATION cellular design cushion insert with a contoured foam base, and is intended to conform to an individual's seated shape in the pelvic loading area to provide skin/soft tissue protection, positioning, and an environment to facilitate wound healing. Optionally, through removal of the IT Air Pad insert, the Hybrid Select is also intended for offloading of the ITs. There is a weight limit of 500 lbs. (227 kg), and the cushion must be properly sized to the individual. The Hybrid Select must be used with the supplied cover.

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

Cushion:	HS1414C	HS1616C	HS1718C	HS2016C
	HS1416C	HS1617C	HS1720C	HS2017C
	HS1515C	HS1618C	HS1816C	HS2018C
	HS1516C	HS1620C	HS1817C	HS2020C
	HS1517C	HS1716C	HS1818C	HSDEMO
	HS1615C	HS1717C	HS1820C	

Basic UDI-DI: 613732NFCV7

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
ISO 15223-1:2021
ISO 16840-6:2015
ANSI/AAMI/IEC 62366-1:2015

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On behalf of ROHO, Inc.



Steven Louer
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