



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® Hybrid Elite® Dual Compartment Cushion
ROHO® Hybrid Elite SR™ Single Compartment Cushion
ROHO® Hybrid Elite® Cushion Cover

General description
Hybrid Elite Cushion
Intended use: The ROHO® Hybrid Elite SR™ Single Compartment Cushion (Hybrid Elite SR) and ROHO® Hybrid Elite® Dual Compartment Cushion (Hybrid Elite Dual Compartment Cushion) 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. There is a weight limit of 500 lbs. (225 kg), and the cushion must be properly sized to the individual. The Hybrid Elite must be used with the supplied cover.

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

Cushion					Covers
1RHE1414C-SR	1RHE2017C-SR	2RHE1414C	2RHE2017C	COV-HE1414	COV-HE2017
1RHE1415C-SR	1RHE2018C-SR	2RHE1415C	2RHE2018C	COV-HE1415	COV-HE2018
1RHE1416C-SR	1RHE2020C-SR	2RHE1416C	2RHE2020C	COV-HE1416	COV-HE2020
1RHE1515C-SR	1RHE2218C-SR	2RHE1515C	2RHE2218C	COV-HE1515	COV-HE2218
1RHE1516C-SR	1RHE2220C-SR	2RHE1516C	2RHE2220C	COV-HE1516	COV-HE2220
1RHE1517C-SR	1RHE2222C-SR	2RHE1517C	2RHE2222C	COV-HE1517	COV-HE2222
1RHE1615C-SR	1RHE2418C-SR	2RHE1615C	2RHE2418C	COV-HE1615	COV-HE2418
1RHE1616C-SR	1RHE2420C-SR	2RHE1616C	2RHE2420C	COV-HE1616	COV-HE2420
1RHE1617C-SR	1RHEHOLG-SR	2RHE1617C	2RHEHD	COV-HE1617	
1RHE1618C-SR	1RHEHD-SR	2RHE1618C	2RHEHOLG	COV-HE1618	
1RHE1620C-SR	1RHEDEMO-SR	2RHE1620C		COV-HE1620	
1RHE1716C-SR		2RHE1716C		COV-HE1716	
1RHE1717C-SR		2RHE1717C		COV-HE1717	
1RHE1718C-SR		2RHE1718C		COV-HE1718	
1RHE1720C-SR		2RHE1720C		COV-HE1720	
1RHE1816C-SR		2RHE1816C		COV-HE1816	
1RHE1817C-SR		2RHE1817C		COV-HE1817	

1RHE1818C-SR

2RHE1818C

COV-HE1818

1RHE1820C-SR

2RHE1820C

COV-HE1820

Basic UDI-DI:

Cushion: 613732NFCV7
Cushion Cover: 613732MCCUR

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

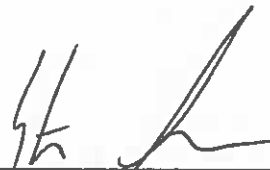
Original drawn up:

2020-10-27

Place and date:

Belleville, Illinois, USA
2024-08-19

On behalf of ROHO, Inc.



Steven Louer
Senior Manager QA/RC