



## 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® CONTOUR SELECT® Cushion

**General description:**

CONTOUR SELECT Cushion

Intended use: The ROHO® CONTOUR SELECT® Cushion (CONTOUR SELECT) is an adjustable, air-filled, cellular-design wheelchair support surface that utilizes DRY FLOATATION® technology and is intended to conform to an individual's seated shape to provide skin/soft tissue protection, positioning, and an environment to facilitate wound healing. There is no weight limit, yet the cushion must be properly sized to the individual.

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

**Cushion**

CS78C	CS1010CF
CS88C	CS1011CF
CS89C	CS109CF
CS810C	CS1110CF
CS98C	CS1111CF
CS99C	CS119CF
CS910C	CS1210CF
CS911C	CS1211CF
CS109C	CS1212CF
CS1010C	CS1310CF
CS1011C	CS1311CF
CS119C	CS78CF
CS1110C	CS810CF
CS1111C	CS88CF
CS1210C	CS89CF
CS1211C	CS910CF
CS1212C	CS911CF
CS1310C	CS98CF
CS1311C	CS99CF
CSLGC	
CSSMC	
CS99DMC	
CSDEMO	

**Basic UDI:**

613732NMC-P7B

**Manufacturer SRN:**

US-MF-000018363



**Authorized representative:** MDSS  
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:** Annex IV EU DECLARATION OF CONFORMITY

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

**Original drawn up:** 2020-10-27

**Place and date:** Belleville, Illinois, USA  
2022-05-24

On behalf of ROHO, Inc.

Robin Gergen  
Director of Quality/Regulatory Compliance