

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:
General description:

ROHO® CONTOUR SELECT® Cushion

CONTOUR SELECT Cushion

Condition

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	
C578C	CS1010CF
CS88C	CS1011CF
CS89C	CS109CF
CS810C	CS1110CF
CS98C	CS1111CF
CS99C	CS119CF
CS910C	CS1210CF
CS911C	CS1211CF
CS109C	C51212CF
CS1010C	CS1310C
CS1011C	CS1311C
CS119C	CS78CF
C51110C	C5810CF
C51111C	CS88CF
CS1210C	CS89CF
CS1211C	CS910CF
CS1212C	CS911CF
CS1310C	CS98CF
CS1311C	CS99CF
CSLGC	
CSSMC	
CS99DMC	
CSDEMO	

Basic UDI-DI:

613732NMC-P7B

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

Sr Manager of Quality/Regulatory Compliance