

## 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® QUADTRO SELECT® HIGH PROFILE® Cushion,  
ROHO® QUADTRO SELECT MID PROFILE™ Cushion,  
ROHO® QUADTRO SELECT LOW PROFILE®

**General description:** QUADTRO SELECT Cushion  
Intended use: Each of the following products: ROHO® QUADTRO SELECT® HIGH PROFILE® Cushion (QUADTRO SELECT HIGH PROFILE), ROHO® QUADTRO SELECT® MID PROFILE™ Cushion (QUADTRO SELECT MID PROFILE), ROHO® QUADTRO SELECT® LOW PROFILE® Cushion (QUADTRO SELECT LOW PROFILE), 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**

QS66C	QS710HD	QS56LPC	QS77MPC
QS67C	QS99HD	QS66LPC	QS78MPC
QS77C	QS910HD	QS67LPC	QS88MPC
QS78C	QS911HD	QS77LPC	QS89MPC
QS79C	QS109HD	QS78LPC	QS99MPC
QS710C	QS1010HD	QS79LPC	QS910MPC
QS87C	QS1011HD	QS87LPC	QS109MPC
QS88C	QS1110HD	QS88LPC	QS1010MPC
QS89C	QS1111HD	QS89LPC	QS1110MPC
QS810C	QS139HD	QS810LPC	QS1111MPC
QS811C	QS1312HD	QS98LPC	QSSMMP
QS98C	QSSMHD	QS99LPC	QSLGMPC
QS99C	QSLGHD	QS910LPC	
QS910C		QS911LPC	
QS911C		QS108LPC	
QS912C		QS109LPC	
QS108C		QS1010LPC	
QS109C		QS1011LPC	
QS1010C		QS119LPC	
QS1011C		QS1110LPC	
QS1012C		QS1111LPC	
QS1013C		QS1210LPC	
QS118C		QS1211LPC	
QS119C		QS1212LPC	
QS1110C		QS1310LPC	
QS1111C		QS1311LPC	
QS1112C		QSSMLPC	

QS1113C  
QS1114C  
QS128C  
QS129C  
QS1210C  
QS1211C  
QS1212C  
QS1213C  
QS1214C  
QS138C  
QS139C  
QS1310C  
QS1311C  
QS1312C  
QS1313C  
QS1314C  
QS148C  
QS149C  
QS1410C  
QS1411C  
QS1412C  
QS1413C  
QSSMC  
QSLGC  
QSLGHD  
QS99DMC  
QS1010DMC  
QSDemo

QSLGLPC  
QS99LPDMC

**Basic UDI:** 613732NMC-P7B

**SRN:** SRN is not assigned. SRN will be assigned when EUDAMED is up and running.

**Authorized representative:** MDSS  
Schiffgraben 41  
30175 Hannover, Germany

**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:** 2020-10-26



**Place and date:** Belleville, Illinois, USA  
2021-04-13

On behalf of ROHO, Inc.

*Kurt Goomey*

4/13/21

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Kurt Goomey  
Vice President of Operations.