



## 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® Cushion

**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	QS1010CF
QS67C	QS99HD	QS66LPC	QS78MPC	QS1010LPCF
QS77C	QS910HD	QS67LPC	QS88MPC	QS1010MPCF
QS78C	QS911HD	QS77LPC	QS89MPC	QS1011CF
QS79C	QS109HD	QS78LPC	QS99MPC	QS1011LPCF
QS710C	QS1010HD	QS79LPC	QS910MPC	QS1012CF
QS87C	QS1011HD	QS87LPC	QS109MPC	QS1013CF
QS88C	QS1110HD	QS88LPC	QS1010MPC	QS108CF
QS89C	QS1111HD	QS89LPC	QS1110MPC	QS108LPCF
QS810C	QS139HD	QS810LPC	QS1111MPC	QS109CF
QS811C	QS1312HD	QS98LPC	QSSMMPC	QS109LPCF
QS98C	QSSMHD	QS99LPC	QSLGMPC	QS109MPCF
QS99C	QSLGHD	QS910LPC		QS1110CF
QS910C	QS1210LPHD	QS911LPC		QS1110LPCF
QS911C	QS119LPHD	QS108LPC		QS1110MPCF
QS912C	QS1310LPHD	QS109LPC		QS1111CF
QS108C	QS1111MPHD	QS1010LPC		QS1111LPCF
QS109C	QS1011LPHD	QS1011LPC		QS1111MPCF
QS1010C	QS118HD	QS119LPC		QS1112CF
QS1011C	QS1211LPHD	QS1110LPC		QS1113CF
QS1012C	QS1013HD	QS1111LPC		QS1114CF
QS1013C	QS129HD	QS1210LPC		QS118CF
QS118C	QS88MPHD	QS1211LPC		QS119CF
QS119C	QS912HD	QS1212LPC		QS119LPCF



QS1110C	QS79LPHD	QS1310LPC	QS1210CF
QS1111C	QS810LPHD	QS1311LPC	QS1210LPCF
QS1112C	QS1110MPHD	QSSMLPC	QS1211CF
QS1113C	QS911LPHD	QSLGLPC	QS1211LPCF
QS1114C	QS98LPHD	QS99LPDMC	QS1212CF
QS128C	QS1010MPHD		QS1212LPCF
QS129C	QS109MPHD		QS1213CF
QS1210C	QS1114HD		QS1214CF
QS1211C	QS128HD		QS128CF
QS1212C	QS138HD		QS129CF
QS1213C	QS1411HD		QS1310CF
QS1214C	QS1412HD		QS1310LPCF
QS138C	QS87LPHD		QS1311CF
QS139C	QS108LPHD		QS1311LPCF
QS1310C	QS1112HD		QS1312CF
QS1311C	QS78MPHD		QS1313CF
QS1312C	QS79HD		QS1314CF
QS1313C	QS89HD		QS138CF
QS1314C	QS89MPHD		QS139CF
QS148C	QS1211HD		QS1410CF
QS149C	QS1212LPHD		QS1411CF
QS1410C	QS77HD		QS1412CF
QS1411C	QS77MPHD		QS1413CF
QS1412C	QS1010LPHD		QS148CF
QS1413C	QS1012HD		QS149CF
QSSMC	QS108HD		QS56LPCF
QSLGC	QS109LPHD		QS66CF
QSLGHD	QS1110LPHD		QS66LPCF
QS99DMC	QS1111LPHD		QS67CF
QS1010DMC	QS1113HD		QS67LPCF
QSDEMO	QS119HD		QS710CF
	QS1210HD		QS77CF
	QS1212HD		QS77LPCF
	QS1213HD		QS77MPCF
	QS1214HD		QS78CF
	QS1310HD		QS78LPCF
	QS1311HD		QS78MPCF
	QS1311LPHD		QS79CF
	QS1313HD		QS79LPCF
	QS1314HD		QS810CF
	QS1410HD		QS810LPCF
	QS1413HD		QS811CF
	QS148HD		QS87CF
	QS149HD		QS87LPCF
	QS66HD		QS88CF
	QS66LPHD		QS88LPCF
	QS67HD		QS88MPCF
	QS67LPHD		QS89CF
	QS77LPHD		QS89LPCF
	QS78HD		QS89MPCF

QS78LPHD  
QS810HD  
QS811HD  
QS87HD  
QS88HD  
QS88LPHD  
QS89LPHD  
QS910LPHD  
QS910MPHD  
QS98HD  
QS99LPHD  
QS99MPHD

QS910CF  
QS910LPCF  
QS910MPCF  
QS911CF  
QS911LPCF  
QS912CF  
QS98CF  
QS98LPCF  
QS99CF  
QS99LPCF  
QS99MPCF

**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 16840-2:2018  
ISO 16840-6:2015

**Original drawn up:** 2020-10-26

**Place and date:** Belleville, Illinois, USA  
2024-08-19



On behalf of ROHO, Inc.

A handwritten signature in black ink, appearing to read 'S. Louer'.

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Steven Louer  
Sr Manager of Quality/Regulatory Compliance