



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	QS910CF
QS810HD	QS910LPCF
QS811HD	QS910MPCF
QS87HD	QS911CF
QS88HD	QS911LPCF
QS88LPHD	QS912CF
QS89LPHD	QS98CF
QS910LPHD	QS98LPCF
QS910MPHD	QS99CF
QS98HD	QS99LPCF
QS99LPHD	QS99MPCF
QS99MPHD	

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: 2020-10-26

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

On behalf of ROHO, Inc.



Robin Gergen

Robin Gergen
Director of Quality/Regulatory Compliance

Prohlášení o shodě EU

Výrobce
ROHO, Inc.

1501 South 74th St.
Belleville, IL 62223 U.S.A.

prohlašuje na svou výhradní odpovědnost, že níže uvedený produkt je ve shodě s

Nařízení (EU) 2017/745

zdravotnických prostředků (MDR)
ROHO, Inc. je dceřinou společností Permobil, Inc.

Název výrobku:

Sedák ROHQ® QUADTRO SELECT® HIGH PROFILE®,
Sedák ROHO® QUADTRO SELECT MID PROFILE™,
Sedák ROHO® QUADTRO SELECT LOW PROFILE®

Obecný popis:

QUADTRO SELECT

Zamýšlené použití: Každý z následujících výrobků: sedák ROHO® QUADTRO SELECT® HIGH PROFILE® (QUADTRO SELECT HIGH PROFILE), sedák ROHO® QUADTRO SELECT MID PROFILE™ (QUADTRO SELECT MID PROFILE), sedák ROHO® QUADTRO SELECT LOW PROFILE® (QUADTRO SELECT LOW PROFILE), je nastavitelný, vzduchem plněný podpůrný sedák pro invalidní vozík s buněčným designem, který využívá technologii DRY FLOATATION®, díky níž se přizpůsobí tvaru sedícího jednotlivce. Poskytuje ochranu kůže/měkkých tkání, polohování a prostředí pro usnadnění hojení ran. Neexistuje žádné omezení hmotnosti uživatele, ale velikost sedáku musí odpovídat potřebám jednotlivce.

Interní číslo/a výrobku výrobce je/Jsou:

Sedák

QS66C	QS710HD	QSS6LPC	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	QSBBLPC	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	QSSI0LPHD	QS1311LPC	QS1210LPCF
QS1112C	QS1110MPHD	QSSMLPC	QS1211CF
QS1113C	QS911LPHD	QSLGLPC	QS1211LPCF
QS1114C	QS98LPHD	QS99LPDMC	QS1212CF
QS128C	QS1010MPHD		QS1212LPCF
QS129C	QS109MPHD		QS1213CF
QS121DC	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		Q556LPCF
QSLGC	QS109LPHD		Q566CF
QSLGHD	QS1110LPHD		Q566LPCF
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		QSSI0CF
	QS1410HD		QS810LPCF
	QS1413HD		QS811CF
	QS148HD		QS87CF
	QS149HD		QS87LPCF
	QS66HD		QSSSCF
	QS66LPHD		QSSSLPCF
	QS67HD		QSSSMPCF
	QS67LPHD		QS89CF
	QS77LPHD		QS89LPCF
	QS78HD		QS89MPCF

QS78LPHD
QS810HD
QS811HD
QS87HD
QSSSHD
QSSSLPHD
QS89LPHD
QS910LPHD
QS910MPHD
QS98HD
QS99LPHD
QS99MPHD

QS910CF
QS910LPCF
QS910MPCF
QS911CF
QS911LPCF
QS912CF
QS98CF
QS98LPCF
QS99CF
QS99LPCF
QS99MPCF

Základní UDI: 613732NMC-P7B

SRN výrobce: US-MF-000018363

Zplnomocněný zástupce: MDSS
Schiffgraben 41
30175 Hannover, Německo

SRN zplnomocněného zástupce: DE-AR-000005430

Klasifikace: Třída I (podle přílohy VIII kapitoly III, pravidla 1)

Použitý postup shody: Příloha IV PROHLÁŠENÍ O SHODĚ EU

Standardy: Shoda s obecnými požadavky na bezpečnost a výkon byla prokázána pomocí následujících norem:
EN 12182:2012
ISO 14971:2012 nebo 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

Originál navržen: 2020-10-26

Místo a datum: Belleville, Illinois, USA
2022-05-24

Jménem společnosti ROHO, Inc.

Robin Gergen

Robin Gergen

Ředitel pro kvalitu/dodržování předpisů