



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® HIGH PROFILE® Single Compartment Cushion. ROHO® HIGH PROFILE® Single Compartment Cushion with Sensor Ready™ Technology. ROHO® LOW PROFILE® Single Compartment Cushion.

General description ROHO® Neoprene Medical Cushion
Intended use: Each of the following products: ROHO HIGH PROFILE Single Compartment Cushion (HIGH PROFILE Single Compartment Cushion); ROHO HIGH PROFILE® Single Compartment Cushion with Sensor Ready Technology (HIGH PROFILE Sensor Ready Cushion); and ROHO LOW PROFILE Single Compartment Cushion (LOW PROFILE Single Compartment Cushion) 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 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				
1R66C	1R99HD	1R66H-CF-SR	1R66LPC	1R1010CF
1R67C	1R910HD	1R66H-CH-SR	1R67LPC	1R1010LPCF
1R77C	1R911HD	1R67H-CF-SR	1R77LPC	1R1011CF
1R78C	1R109HD	1R67H-CH-SR	1R78LPC	1R1011LPCF
1R79C	1R1010HD	1R77H-CF-SR	1R79LPC	1R1012CF
1R87C	1R1011HD	1R77H-CH-SR	1R87LPC	1R1013CF
1R88C	1R1110HD	1R78H-CF-SR	1R88LPC	1R1014CF
1R89C	1R1111HD	1R78H-CH-SR	1R89LPC	1R108CF
1R810C	1R1210HD	1R79H-CF-SR	1R810LPC	1R108LPCF
1R811C	1R1211HD	1R79H-CH-SR	1R98LPC	1R109CF
1R98C	1RSMHD	1R87H-CF-SR	1R99LPC	1R109LPCF
1R99C	1RLGHD	1R87H-CH-SR	1R910LPC	1R1110CF
1R910C		1R88H-CF-SR	1R911LPC	1R1110LPCF
1R911C		1R88H-CH-SR	1R108LPC	1R1111CF
1R912C		1R89H-CF-SR	1R109LPC	1R1111LPCF
1R108C		1R89H-CH-SR	1R1010LPC	1R1112CF
1R109C		1R810H-CF-SR	1R1011LPC	1R1113CF
1R1010C		1R810H-CH-SR	1R119LPC	1R1114CF
1R1011C		1R98H-CF-SR	1R1110LPC	1R118CF
1R1012C		1R98H-CH-SR	1R1111LPC	1R119CF



1R1013C	1R99H-CF-SR	1R1210LPC	1R119LPCF
1R1014C	1R99H-CH-SR	1R1310LPC	1R1210CF
1R118C	1R910H-CF-SR	1RSM LPC	1R1210LPCF
1R119C	1R910H-CH-SR	1RLGLPC	1R1211CF
1R1110C	1R911H-CF-SR	1RSCF-DEMO	1R1212CF
1R1111C	1R911H-CH-SR	1RSCH-DEMO	1R1213CF
1R1112C	1R108H-CF-SR		1R1214CF
1R1113C	1R108H-CH-SR		1R128CF
1R1114C	1R109H-CF-SR		1R129CF
1R128C	1R109H-CH-SR		1R1310CF
1R129C	1R1010H-CF-SR		1R1310LPCF
1R1210C	1R1010H-CH-SR		1R1311CF
1R1211C	1R1011H-CF-SR		1R1312CF
1R1212C	1R1011H-CH-SR		1R1313CF
1R1213C	1R1012H-CF-SR		1R1314CF
1R1214C	1R1012H-CH-SR		1R138CF
1R138C	1R119H-CF-SR		1R139CF
1R139C	1R119H-CH-SR		1R1410CF
1R1310C	1R1110H-CF-SR		1R1411CF
1R1311C	1R1110H-CH-SR		1R1412CF
1R1312C	1R1111H-CF-SR		1R1413CF
1R1313C	1R1111H-CH-SR		1R1414CF
1R1314C	1R1112H-CF-SR		1R148CF
1R148C	1R1112H-CH-SR		1R149CF
1R149C	1R129H-CF-SR		1R1511CF
1R1410C	1R129H-CH-SR		1R66CF
1R1411C	1R1210H-CF-SR		1R66LPCF
1R1412C	1R1210H-CH-SR		1R67CF
1R1413C	1R1211H-CF-SR		1R67LPCF
1R1414C	1R1211H-CH-SR		1R77CF
1R1511C	1R1212H-CF-SR		1R77LPCF
1RSMC	1R1212H-CH-SR		1R78CF
1RLGC	1R1310H-CF-SR		1R78LPCF
HPDEMO	1R1310H-CH-SR		1R79CF
	1R1311H-CF-SR		1R79LPCF
	1R1311H-CH-SR		1R810CF
	1R1411H-CF-SR		1R810LPCF
	1R1411H-CH-SR		1R811CF
	1R1511H-CF-SR		1R87CF
	1R1511H-CH-SR		1R87LPCF
	1R1010H-CF-SCDM		1R88CF
	1R109H-CF-SCDM		1R88LPCF
	1R99H-CF-SCDM		1R89CF
			1R89LPCF
			1R910CF
			1R910LPCF
			1R911CF
			1R911LPCF
			1R912CF
			1R98CF

Basic UDI: Cushion: 613732NMCVU

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
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 prostředcích (MDR)
ROHO, Inc. je dceřinou společností Permobil, Inc.

Název výrobku:

Sedák ROHO® jednokomorový HIGH PROFILE®
Sedák ROHO® jednokomorový HIGH PROFILE® s technologií Sensor Ready™,
Sedák ROHO® jednokomorový LOW PROFILE®

Obecný popis:

Neoprenový medicínský sedák ROHO®
Zamýšlené použití: Každý z následujících výrobků: Sedák ROHO jednokomorový HIGH PROFILE (HIGH PROFILE Single Compartment Cushion); sedák ROHO jednokomorový HIGH PROFILE® s technologií Sensor Ready (HIGH PROFILE Sensor Ready Cushion); a sedák ROHO jednokomorový LOW PROFILE (LOW PROFILE Single Compartment Cushion), 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

1R66C	1R99HD	1R66H-CF-SR	1R66LPC	1R1010CF
1R67C	1R910HD	1R66H-CH-SR	1R67LPC	1R1010LPCF
1R77C	1R911HD	1R67H-CF-SR	1R77LPC	1R1011CF
1R78C	1R109HD	1R67H-CH-SR	1R78LPC	1R1011LPCF
1R79C	1R1010HD	1R77H-CF-SR	1R79LPC	1R1012CF
1R87C	1R1011HD	1R77H-CH-SR	1R87LPC	1R1013CF
1R88C	1R1110HD	1R78H-CF-SR	1R88LPC	1R1014CF
1R89C	1R1111HD	1R78H-CH-SR	1R89LPC	1R108CF
1R810C	1R1210HD	1R79H-CF-SR	1R810LPC	1R108LPCF
1R811C	1R1211HD	1R79H-CH-SR	1R98LPC	1R109CF
1R98C	1RSMHD	1R87H-CF-SR	1R99LPC	1R109LPCF
1R99C	1RLGHD	1R87H-CH-SR	1R910LPC	1R1110CF
1R910C		1R88H-CF-SR	1R911LPC	1R1110LPCF
1R911C		1R88H-CH-SR	1R108LPC	1R1111CF
1R912C		1R89H-CF-SR	1R109LPC	1R1111LPCF
1R108C		1R89H-CH-SR	1R1010LPC	1R1112CF
1R109C		1R810H-CF-SR	1R1011LPC	1R1113CF
1R1010C		1R810H-CH-SR	1R119LPC	1R1114CF
1R1011C		1R98H-CF-SR	1R1110LPC	1R118CF
1R1012C		1R98H-CH-SR	1R1111LPC	1R119CF

1R1014C
1R115C
1R119C
1R1110C
1R1111C
1R1112C
1R1113C
1R1114C
1R128C
1R129C
1R1210C
1R1211C
1R1212C
1R1213C
1R1214C
1R138C
1R139C
1R1310C
1R1311C
1R1312C
1R1313C
1R1314C
1R148C
1R149C
1R1410C
1R1411C
1R1412C
1R1413C
1R1414C
1R1511C
1RSMC
1RLGC
HPDEMO

1R99H-CF-SR
1R99H-CH-SR
1R910H-CF-SR
1R910H-CH-SR
1R911H-CF-SR
1R911H-CH-SR
1R108H-CF-SR
1R108H-CH-SR
1R109H-CF-SR
1R109H-CH-SR

1R1010H-CF-SR
1R1010H-CH-SR
1R1011H-CF-SR
1R1011H-CH-SR
1R1012H-CF-SR
1R1012H-CH-SR

1R119H-CF-SR
1R119H-CH-SR
1R1110H-CF-SR
1R1110H-CH-SR
1R1111H-CF-SR
1R1111H-CH-SR
1R1112H-CF-SR
1R1112H-CH-SR

1R129H-CF-SR
1R129H-CH-SR
1R1210H-CF-SR
1R1210H-CH-SR
1R1211H-CF-SR
1R1211H-CH-SR
1R1212H-CF-SR
1R1212H-CH-SR
1R1310H-CF-SR
1R1310H-CH-SR
1R1311H-CF-SR
1R1311H-CH-SR
1R1411H-CF-SR
1R1411H-CH-SR
1R1511H-CF-SR
1R1511H-CH-SR
1R1010H-CF-SCDM
1R109H-CF-SCDM
1R99H-CF-SCDM

1R1210LPC
1R1310LPC
1RSMLPC
1RLGLPC
1RSCF-DEMO
1RSCH-DEMO

1R119LPCF
1R1210CF
1R1210LPCF
1R1211CF
1R1212CF
1R1213CF
1R1214CF
1R128CF
1R129CF
1R1310CF
1R1310LPCF
1R1311CF
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1R1314CF
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1R139CF
1R1410CF
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1R1412CF
1R1413CF
1R1414CF
1R148CF
1R149CF
1R1511CF
1R66CF
1R66LPCF
1R67CF
1R67LPCF
1R77CF
1R77LPCF
1R78CF
1R78LPCF
1R79CF
1R79LPCF
1R810CF
1R810LPCF
1R811CF
1R87CF
1R87LPCF
1R88CF
1R88LPCF
1R89CF
1R89LPCF
1R910CF
1R910LPCF
1R911CF
1R911LPCF
1R912CF
1R98CF

Základní UDI: 613732NMCVU

SRN výrobce: US-MF-000018363

Zplnomocněný zástupce: MDSS
Schiffgraben 41
30175 Hannover, Německo

SRN zplnomocněného zástupce OE-AR-000005430

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

**Použitý postup shody:
Standardy:** Příloha IV PROHLÁŠENÍ O SHODĚ EU
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
Ředitel pro kvalitu/dodržování předpisů