



EU-declaration of conformity

As manufacturer
The Comfort Companies, LLC
1960 S Calhoun Road
New Berlin, WI 53151

declares under the sole responsibility that below specified product is in conformity with the

Regulation (EU) 2017/745
on medical devices (MDR)

The Comfort Companies, LLC is a subsidiary of Permobil, Inc.

Trade Name: Comfort M2 Cushion, Comfort Cushion Cover
General description: Comfort Company Medical Foam Cushion and Cover

Intended use:

The Comfort M2 Cushion (M2) is a ready-to-use wheelchair seating surface, intended to promote postural alignment and pelvic stability while reducing peak pressures in high risk areas such as the ITs, coccyx, and sacrum. The M2 is intended for those who are at risk of developing pressure injuries. The M2 must be properly sized to the individual and must be used with a compatible cover. The M2 has a weight limit of 200 to 400 pounds.

The Comfort Cushion Cover is a device intended to cover a medical cushion during use to protect the cushion from dirt/debris.



The manufacturer's internal article number(s) is/are:

M2

Cushion w/ Stretch-Air

M2-FRSA-10W10D
M2-FRSA-10W11D
M2-FRSA-10W12D
M2-FRSA-10W13D
M2-FRSA-10W14D
M2-FRSA-10W15D
M2-FRSA-10W16D
M2-FRSA-11W10D
M2-FRSA-11W11D
M2-FRSA-11W12D
M2-FRSA-11W13D
M2-FRSA-11W14D
M2-FRSA-11W15D
M2-FRSA-11W16D
M2-FRSA-11W17D
M2-FRSA-12W10D
M2-FRSA-12W11D
M2-FRSA-12W12D
M2-FRSA-12W13D
M2-FRSA-12W14D
M2-FRSA-12W15D
M2-FRSA-12W16D
M2-FRSA-12W17D
M2-FRSA-12W18D
M2-FRSA-13W10D
M2-FRSA-13W11D
M2-FRSA-13W12D
M2-FRSA-13W13D
M2-FRSA-13W14D
M2-FRSA-13W15D
M2-FRSA-13W16D
M2-FRSA-13W17D
M2-FRSA-13W18D
M2-FRSA-14W10D
M2-FRSA-14W11D
M2-FRSA-14W12D
M2-FRSA-14W13D
M2-FRSA-14W14D
M2-FRSA-14W15D
M2-FRSA-14W16D
M2-FRSA-14W17D
M2-FRSA-14W18D
M2-FRSA-14W19D
M2-FRSA-14W20D
M2-FRSA-15W10D
M2-FRSA-15W11D
M2-FRSA-15W12D
M2-FRSA-15W13D
M2-FRSA-15W14D
M2-FRSA-15W15D

Cover - Stretch-Air

M2-FRFA-10W10D-CV
M2-FRFA-10W11D-CV
M2-FRFA-10W12D-CV
M2-FRFA-10W13D-CV
M2-FRFA-10W14D-CV
M2-FRFA-10W15D-CV
M2-FRFA-10W16D-CV
M2-FRFA-11W10D-CV
M2-FRFA-11W11D-CV
M2-FRFA-11W12D-CV
M2-FRFA-11W13D-CV
M2-FRFA-11W14D-CV
M2-FRFA-11W15D-CV
M2-FRFA-11W16D-CV
M2-FRFA-11W17D-CV
M2-FRFA-12W10D-CV
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M2-FRFA-14W19D-CV
M2-FRFA-14W20D-CV
M2-FRFA-15W10D-CV
M2-FRFA-15W11D-CV
M2-FRFA-15W12D-CV
M2-FRFA-15W13D-CV
M2-FRFA-15W14D-CV
M2-FRFA-15W15D-CV

Cover - Comfort-Tek

M2-FRSA-10W10D-CV
M2-FRSA-10W11D-CV
M2-FRSA-10W12D-CV
M2-FRSA-10W13D-CV
M2-FRSA-10W14D-CV
M2-FRSA-10W15D-CV
M2-FRSA-10W16D-CV
M2-FRSA-11W10D-CV
M2-FRSA-11W11D-CV
M2-FRSA-11W12D-CV
M2-FRSA-11W13D-CV
M2-FRSA-11W14D-CV
M2-FRSA-11W15D-CV
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M2-FRSA-12W10D-CV
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M2-FRSA-14W19D-CV
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M2-FRSA-15W10D-CV
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M2-FRSA-15W15D-CV



M2-FRSA-15W16D	M2-FRFA-15W16D-CV	M2-FRSA-15W16D-CV
M2-FRSA-15W17D	M2-FRFA-15W17D-CV	M2-FRSA-15W17D-CV
M2-FRSA-15W18D	M2-FRFA-15W18D-CV	M2-FRSA-15W18D-CV
M2-FRSA-15W19D	M2-FRFA-15W19D-CV	M2-FRSA-15W19D-CV
M2-FRSA-15W20D	M2-FRFA-15W20D-CV	M2-FRSA-15W20D-CV
M2-FRSA-15W21D	M2-FRFA-15W21D-CV	M2-FRSA-15W21D-CV
M2-FRSA-16W12D	M2-FRFA-16W12D-CV	M2-FRSA-16W12D-CV
M2-FRSA-16W13D	M2-FRFA-16W13D-CV	M2-FRSA-16W13D-CV
M2-FRSA-16W14D	M2-FRFA-16W14D-CV	M2-FRSA-16W14D-CV
M2-FRSA-16W15D	M2-FRFA-16W15D-CV	M2-FRSA-16W15D-CV
M2-FRSA-16W16D	M2-FRFA-16W16D-CV	M2-FRSA-16W16D-CV
M2-FRSA-16W17D	M2-FRFA-16W17D-CV	M2-FRSA-16W17D-CV
M2-FRSA-16W18D	M2-FRFA-16W18D-CV	M2-FRSA-16W18D-CV
M2-FRSA-16W19D	M2-FRFA-16W19D-CV	M2-FRSA-16W19D-CV
M2-FRSA-16W20D	M2-FRFA-16W20D-CV	M2-FRSA-16W20D-CV
M2-FRSA-16W21D	M2-FRFA-16W21D-CV	M2-FRSA-16W21D-CV
M2-FRSA-16W22D	M2-FRFA-16W22D-CV	M2-FRSA-16W22D-CV
M2-FRSA-17W12D	M2-FRFA-17W12D-CV	M2-FRSA-17W12D-CV
M2-FRSA-17W13D	M2-FRFA-17W13D-CV	M2-FRSA-17W13D-CV
M2-FRSA-17W14D	M2-FRFA-17W14D-CV	M2-FRSA-17W14D-CV
M2-FRSA-17W15D	M2-FRFA-17W15D-CV	M2-FRSA-17W15D-CV
M2-FRSA-17W16D	M2-FRFA-17W16D-CV	M2-FRSA-17W16D-CV
M2-FRSA-17W17D	M2-FRFA-17W17D-CV	M2-FRSA-17W17D-CV
M2-FRSA-17W18D	M2-FRFA-17W18D-CV	M2-FRSA-17W18D-CV
M2-FRSA-17W19D	M2-FRFA-17W19D-CV	M2-FRSA-17W19D-CV
M2-FRSA-17W20D	M2-FRFA-17W20D-CV	M2-FRSA-17W20D-CV
M2-FRSA-17W21D	M2-FRFA-17W21D-CV	M2-FRSA-17W21D-CV
M2-FRSA-17W22D	M2-FRFA-17W22D-CV	M2-FRSA-17W22D-CV
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M2-FRSA-18W18D	M2-FRFA-18W18D-CV	M2-FRSA-18W18D-CV
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M2-FRSA-18W22D	M2-FRFA-18W22D-CV	M2-FRSA-18W22D-CV
M2-FRSA-18W23D	M2-FRFA-18W23D-CV	M2-FRSA-18W23D-CV
M2-FRSA-18W24D	M2-FRFA-18W24D-CV	M2-FRSA-18W24D-CV
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M2-FRSA-20W19D	M2-FRFA-20W19D-CV	M2-FRSA-20W19D-CV
M2-FRSA-20W20D	M2-FRFA-20W20D-CV	M2-FRSA-20W20D-CV
M2-FRSA-20W21D	M2-FRFA-20W21D-CV	M2-FRSA-20W21D-CV



M2-FRSA-20W22D	M2-FRFA-20W22D-CV	M2-FRSA-20W22D-CV
M2-FRSA-20W23D	M2-FRFA-20W23D-CV	M2-FRSA-20W23D-CV
M2-FRSA-20W24D	M2-FRFA-20W24D-CV	M2-FRSA-20W24D-CV
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M2-FRSA-23W19D	M2-FRFA-23W19D-CV	M2-FRSA-23W19D-CV
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M2-FRSA-24W16D	M2-FRFA-24W16D-CV	M2-FRSA-24W16D-CV
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M2-FRSA-24W22D	M2-FRFA-24W22D-CV	M2-FRSA-24W22D-CV
M2-FRSA-24W23D	M2-FRFA-24W23D-CV	M2-FRSA-24W23D-CV
M2-FRSA-24W24D	M2-FRFA-24W24D-CV	M2-FRSA-24W24D-CV

Basic UDI:

Cushion: 0194637FMCAU

Cover: 0194637MCCAZ

Manufacturer SRN:

US-MF-000032945

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:
Standards:

Annex IV EU DECLARATION OF CONFORMITY
Conformity to the general safety and performance requirements have been demonstrated by using the following standards:

ISO 14971:2012 or 2019	ISO 10993-10:2013
ISO 13485:2016	AfPS GS 2014:01
EN 12182:2012	ISO 13732-1:2008
ISO 10993-5:2009	ISO 15223-1:2016
EN 1021-1 & -2:2014	ISO 16840-6:2015

Original drawn up:

18 November 2020

Place and date:

New Berlin, Wisconsin, USA
03 March 2023

On behalf of The Comfort Companies, LLC

Robin Gergen
Director Regulatory Compliance