



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 Curve® Cushion, Comfort Acta-Embrace™ Cushion,
Comfort Cushion Cover

General description: Comfort Company Medical Foam Cushion and Cover

Intended use:

The Comfort Acta-Embrace Cushion (Acta-Embrace) is a ready-to-use wheelchair seating surface, intended to promote postural alignment and pelvic stability and to provide skin protection and comfort. The Acta-Embrace is intended for those who are at risk of developing pressure injuries. The Acta-Embrace must be properly sized to the individual and must be used with a compatible cover. The Acta-Embrace has a weight limit of 200 to 400 pounds.

The Comfort Curve Cushion (Curve) is a lightweight and ready-to-use wheelchair seating surface, intended to promote pressure redistribution and provide a stable and comfortable seating surface. The Curve must be properly sized to the individual and must be used with a compatible cover. The Curve has a weight limit of 100 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:

Embrace

Cushion w/ Stretch-Air

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

Cover - Stretch-Air

EM-FRFA-10W10D-CV
EM-FRFA-10W11D-CV
EM-FRFA-10W12D-CV
EM-FRFA-10W13D-CV
EM-FRFA-10W14D-CV
EM-FRFA-10W15D-CV
EM-FRFA-10W16D-CV
EM-FRFA-11W10D-CV
EM-FRFA-11W11D-CV
EM-FRFA-11W12D-CV
EM-FRFA-11W13D-CV
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EM-FRFA-14W20D-CV
EM-FRFA-15W10D-CV
EM-FRFA-15W11D-CV
EM-FRFA-15W12D-CV
EM-FRFA-15W13D-CV
EM-FRFA-15W14D-CV
EM-FRFA-15W15D-CV
EM-FRFA-15W16D-CV

Cover - Comfort-Tek

EM-FRSA-10W10D-CV
EM-FRSA-10W11D-CV
EM-FRSA-10W12D-CV
EM-FRSA-10W13D-CV
EM-FRSA-10W14D-CV
EM-FRSA-10W15D-CV
EM-FRSA-10W16D-CV
EM-FRSA-11W10D-CV
EM-FRSA-11W11D-CV
EM-FRSA-11W12D-CV
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EM-FRSA-15W19D	EM-FRFA-15W19D-CV	EM-FRSA-15W19D-CV
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EM-FRSA-15W21D	EM-FRFA-15W21D-CV	EM-FRSA-15W21D-CV
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EM-FRSA-18W16D	EM-FRFA-18W16D-CV	EM-FRSA-18W16D-CV
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EM-FRSA-18W23D	EM-FRFA-18W23D-CV	EM-FRSA-18W23D-CV
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EM-FRSA-20W23D	EM-FRFA-20W23D-CV	EM-FRSA-20W23D-CV



EM-FRSA-20W24D	EM-FRFA-20W24D-CV	EM-FRSA-20W24D-CV
EM-FRSA-21W16D	EM-FRFA-21W16D-CV	EM-FRSA-21W16D-CV
EM-FRSA-21W17D	EM-FRFA-21W17D-CV	EM-FRSA-21W17D-CV
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EM-FRSA-24W21D	EM-FRFA-24W21D-CV	EM-FRSA-24W21D-CV
EM-FRSA-24W22D	EM-FRFA-24W22D-CV	EM-FRSA-24W22D-CV
EM-FRSA-24W23D	EM-FRFA-24W23D-CV	EM-FRSA-24W23D-CV
EM-FRSA-24W24D	EM-FRFA-24W24D-CV	EM-FRSA-24W24D-CV

Curve

Cushion w/ Stretch-Air	Cover - Stretch-Air	Cushion w/ Comfort-Tek	Cover - Comfort-Tek
CU-FRS-10W10D	CU-FRS-10W10D-CV	CU-FRF-10W10D	CU-FRF-10W10D-CV
CU-FRS-10W11D	CU-FRS-10W11D-CV	CU-FRF-10W11D	CU-FRF-10W11D-CV
CU-FRS-10W12D	CU-FRS-10W12D-CV	CU-FRF-10W12D	CU-FRF-10W12D-CV
CU-FRS-10W13D	CU-FRS-10W13D-CV	CU-FRF-10W13D	CU-FRF-10W13D-CV
CU-FRS-10W14D	CU-FRS-10W14D-CV	CU-FRF-10W14D	CU-FRF-10W14D-CV
CU-FRS-10W15D	CU-FRS-10W15D-CV	CU-FRF-10W15D	CU-FRF-10W15D-CV
CU-FRS-11W10D	CU-FRS-11W10D-CV	CU-FRF-11W10D	CU-FRF-11W10D-CV
CU-FRS-11W11D	CU-FRS-11W11D-CV	CU-FRF-11W11D	CU-FRF-11W11D-CV
CU-FRS-11W12D	CU-FRS-11W12D-CV	CU-FRF-11W12D	CU-FRF-11W12D-CV
CU-FRS-11W13D	CU-FRS-11W13D-CV	CU-FRF-11W13D	CU-FRF-11W13D-CV
CU-FRS-11W14D	CU-FRS-11W14D-CV	CU-FRF-11W14D	CU-FRF-11W14D-CV
CU-FRS-11W15D	CU-FRS-11W15D-CV	CU-FRF-11W15D	CU-FRF-11W15D-CV
CU-FRS-12W10D	CU-FRS-12W10D-CV	CU-FRF-12W10D	CU-FRF-12W10D-CV
CU-FRS-12W11D	CU-FRS-12W11D-CV	CU-FRF-12W11D	CU-FRF-12W11D-CV
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CU-FRS-12W14D	CU-FRS-12W14D-CV	CU-FRF-12W14D	CU-FRF-12W14D-CV



CU-FRS-12W15D	CU-FRS-12W15D-CV	CU-FRF-12W15D	CU-FRF-12W15D-CV
CU-FRS-12W16D	CU-FRS-12W16D-CV	CU-FRF-12W16D	CU-FRF-12W16D-CV
CU-FRS-13W10D	CU-FRS-13W10D-CV	CU-FRF-13W10D	CU-FRF-13W10D-CV
CU-FRS-13W11D	CU-FRS-13W11D-CV	CU-FRF-13W11D	CU-FRF-13W11D-CV
CU-FRS-13W12D	CU-FRS-13W12D-CV	CU-FRF-13W12D	CU-FRF-13W12D-CV
CU-FRS-13W13D	CU-FRS-13W13D-CV	CU-FRF-13W13D	CU-FRF-13W13D-CV
CU-FRS-13W14D	CU-FRS-13W14D-CV	CU-FRF-13W14D	CU-FRF-13W14D-CV
CU-FRS-13W15D	CU-FRS-13W15D-CV	CU-FRF-13W15D	CU-FRF-13W15D-CV
CU-FRS-13W16D	CU-FRS-13W16D-CV	CU-FRF-13W16D	CU-FRF-13W16D-CV
CU-FRS-13W17D	CU-FRS-13W17D-CV	CU-FRF-13W17D	CU-FRF-13W17D-CV
CU-FRS-14W10D	CU-FRS-14W10D-CV	CU-FRF-14W10D	CU-FRF-14W10D-CV
CU-FRS-14W11D	CU-FRS-14W11D-CV	CU-FRF-14W11D	CU-FRF-14W11D-CV
CU-FRS-14W12D	CU-FRS-14W12D-CV	CU-FRF-14W12D	CU-FRF-14W12D-CV
CU-FRS-14W13D	CU-FRS-14W13D-CV	CU-FRF-14W13D	CU-FRF-14W13D-CV
CU-FRS-14W14D	CU-FRS-14W14D-CV	CU-FRF-14W14D	CU-FRF-14W14D-CV
CU-FRS-14W15D	CU-FRS-14W15D-CV	CU-FRF-14W15D	CU-FRF-14W15D-CV
CU-FRS-14W16D	CU-FRS-14W16D-CV	CU-FRF-14W16D	CU-FRF-14W16D-CV
CU-FRS-14W17D	CU-FRS-14W17D-CV	CU-FRF-14W17D	CU-FRF-14W17D-CV
CU-FRS-14W18D	CU-FRS-14W18D-CV	CU-FRF-14W18D	CU-FRF-14W18D-CV
CU-FRS-15W14D	CU-FRS-15W14D-CV	CU-FRF-15W14D	CU-FRF-15W14D-CV
CU-FRS-15W15D	CU-FRS-15W15D-CV	CU-FRF-15W15D	CU-FRF-15W15D-CV
CU-FRS-15W16D	CU-FRS-15W16D-CV	CU-FRF-15W16D	CU-FRF-15W16D-CV
CU-FRS-15W17D	CU-FRS-15W17D-CV	CU-FRF-15W17D	CU-FRF-15W17D-CV
CU-FRS-15W18D	CU-FRS-15W18D-CV	CU-FRF-15W18D	CU-FRF-15W18D-CV
CU-FRS-15W19D	CU-FRS-15W19D-CV	CU-FRF-15W19D	CU-FRF-15W19D-CV
CU-FRS-15W20D	CU-FRS-15W20D-CV	CU-FRF-15W20D	CU-FRF-15W20D-CV
CU-FRS-16W14D	CU-FRS-16W14D-CV	CU-FRF-16W14D	CU-FRF-16W14D-CV
CU-FRS-16W15D	CU-FRS-16W15D-CV	CU-FRF-16W15D	CU-FRF-16W15D-CV
CU-FRS-16W16D	CU-FRS-16W16D-CV	CU-FRF-16W16D	CU-FRF-16W16D-CV
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CU-FRS-16W18D	CU-FRS-16W18D-CV	CU-FRF-16W18D	CU-FRF-16W18D-CV
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CU-FRS-16W20D	CU-FRS-16W20D-CV	CU-FRF-16W20D	CU-FRF-16W20D-CV
CU-FRS-17W15D	CU-FRS-17W15D-CV	CU-FRF-17W15D	CU-FRF-17W15D-CV
CU-FRS-17W16D	CU-FRS-17W16D-CV	CU-FRF-17W16D	CU-FRF-17W16D-CV
CU-FRS-17W17D	CU-FRS-17W17D-CV	CU-FRF-17W17D	CU-FRF-17W17D-CV
CU-FRS-17W18D	CU-FRS-17W18D-CV	CU-FRF-17W18D	CU-FRF-17W18D-CV
CU-FRS-17W19D	CU-FRS-17W19D-CV	CU-FRF-17W19D	CU-FRF-17W19D-CV
CU-FRS-17W20D	CU-FRS-17W20D-CV	CU-FRF-17W20D	CU-FRF-17W20D-CV
CU-FRS-18W15D	CU-FRS-18W15D-CV	CU-FRF-18W15D	CU-FRF-18W15D-CV
CU-FRS-18W16D	CU-FRS-18W16D-CV	CU-FRF-18W16D	CU-FRF-18W16D-CV
CU-FRS-18W17D	CU-FRS-18W17D-CV	CU-FRF-18W17D	CU-FRF-18W17D-CV
CU-FRS-18W18D	CU-FRS-18W18D-CV	CU-FRF-18W18D	CU-FRF-18W18D-CV
CU-FRS-18W19D	CU-FRS-18W19D-CV	CU-FRF-18W19D	CU-FRF-18W19D-CV
CU-FRS-18W20D	CU-FRS-18W20D-CV	CU-FRF-18W20D	CU-FRF-18W20D-CV
CU-FRS-19W16D	CU-FRS-19W16D-CV	CU-FRF-19W16D	CU-FRF-19W16D-CV
CU-FRS-19W17D	CU-FRS-19W17D-CV	CU-FRF-19W17D	CU-FRF-19W17D-CV
CU-FRS-19W18D	CU-FRS-19W18D-CV	CU-FRF-19W18D	CU-FRF-19W18D-CV
CU-FRS-19W19D	CU-FRS-19W19D-CV	CU-FRF-19W19D	CU-FRF-19W19D-CV
CU-FRS-19W20D	CU-FRS-19W20D-CV	CU-FRF-19W20D	CU-FRF-19W20D-CV
CU-FRS-20W16D	CU-FRS-20W16D-CV	CU-FRF-20W16D	CU-FRF-20W16D-CV
CU-FRS-20W17D	CU-FRS-20W17D-CV	CU-FRF-20W17D	CU-FRF-20W17D-CV
CU-FRS-20W18D	CU-FRS-20W18D-CV	CU-FRF-20W18D	CU-FRF-20W18D-CV
CU-FRS-20W19D	CU-FRS-20W19D-CV	CU-FRF-20W19D	CU-FRF-20W19D-CV
CU-FRS-20W20D	CU-FRS-20W20D-CV	CU-FRF-20W20D	CU-FRF-20W20D-CV
CU-FRS-21W16D	CU-FRS-21W16D-CV	CU-FRF-21W16D	CU-FRF-21W16D-CV
CU-FRS-21W17D	CU-FRS-21W17D-CV	CU-FRF-21W17D	CU-FRF-21W17D-CV
CU-FRS-21W18D	CU-FRS-21W18D-CV	CU-FRF-21W18D	CU-FRF-21W18D-CV



CU-FRS-21W19D	CU-FRS-21W19D-CV	CU-FRF-21W19D	CU-FRF-21W19D-CV
CU-FRS-21W20D	CU-FRS-21W20D-CV	CU-FRF-21W20D	CU-FRF-21W20D-CV
CU-FRS-22W16D	CU-FRS-22W16D-CV	CU-FRF-22W16D	CU-FRF-22W16D-CV
CU-FRS-22W17D	CU-FRS-22W17D-CV	CU-FRF-22W17D	CU-FRF-22W17D-CV
CU-FRS-22W18D	CU-FRS-22W18D-CV	CU-FRF-22W18D	CU-FRF-22W18D-CV
CU-FRS-22W19D	CU-FRS-22W19D-CV	CU-FRF-22W19D	CU-FRF-22W19D-CV
CU-FRS-22W20D	CU-FRS-22W20D-CV	CU-FRF-22W20D	CU-FRF-22W20D-CV
CU-FRS-23W16D	CU-FRS-23W16D-CV	CU-FRF-23W16D	CU-FRF-23W16D-CV
CU-FRS-23W17D	CU-FRS-23W17D-CV	CU-FRF-23W17D	CU-FRF-23W17D-CV
CU-FRS-23W18D	CU-FRS-23W18D-CV	CU-FRF-23W18D	CU-FRF-23W18D-CV
CU-FRS-23W19D	CU-FRS-23W19D-CV	CU-FRF-23W19D	CU-FRF-23W19D-CV
CU-FRS-23W20D	CU-FRS-23W20D-CV	CU-FRF-23W20D	CU-FRF-23W20D-CV
CU-FRS-24W16D	CU-FRS-24W16D-CV	CU-FRF-24W16D	CU-FRF-24W16D-CV
CU-FRS-24W17D	CU-FRS-24W17D-CV	CU-FRF-24W17D	CU-FRF-24W17D-CV
CU-FRS-24W18D	CU-FRS-24W18D-CV	CU-FRF-24W18D	CU-FRF-24W18D-CV
CU-FRS-24W19D	CU-FRS-24W19D-CV	CU-FRF-24W19D	CU-FRF-24W19D-CV
CU-FRS-24W20D	CU-FRS-24W20D-CV	CU-FRF-24W20D	CU-FRF-24W20D-CV

Basic UDI: Cushion: 0194637FMCAU
Cover: 0194637MCCAZ

Manufacturer SRN: US-MF-000032945

Authorized representative: MDSS
Schiffgraben 41
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Authorized representative SRN: DE-AR-000005430

Product class: Class I (according to Annex VIII Chapter III, rule 1)

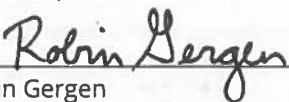
Conformity procedure used: Annex IV EU DECLARATION OF CONFORMITY
Standards: Conformity to the general safety and performance requirements have been demonstrated by using the following standards:

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

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03 March 2023

On behalf of The Comfort Companies, LLC



Robin Gerger
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