

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 Unite 1 Back Support, Comfort Unite 2 Back Support, Comfort Unite 3 Back Support, Comfort Embrace Back Support, Comfort Relief Back Support

General description: Comfort Back Supports

Intended use:

Comfort Unite Back Supports (Comfort Unite 1 Back Support, Comfort Unite 2 Back Support, Comfort Unite 3 Back Support) are back support devices that are intended to provide trunk support and positioning for wheelchair users. Comfort Unite Back Supports have a weight limit of up to 300lbs (136kg) and must be properly sized for the individual. Comfort Unite Back Supports are available in the sizes 12 in. – 20 in. (30.5 cm – 51 cm) in Width (increments of 2 in. (5 cm)).

Comfort Embrace Back Supports are planar back support devices that are intended to provide trunk support and positioning for wheelchair users. The Comfort Embrace has a weight limit of up to 250lbs (113kg) and must be properly sized for the individual. The Comfort Embrace Back Supports are available in sizes 10 in. – 14 in. (25 cm – 35.5 cm) in Width (increments of 2 in. (5 cm)).

Comfort Relief Back Supports are back support devices that are intended to provide trunk support and positioning for wheelchair users. The back supports utilize an adjustable cable system to allow for individualized contouring of the back depth. Comfort Relief has a weight limit of 300lbs (136kg) and must be properly sized for the individual. The Comfort Relief Back Supports are available in the sizes 14 in. – 20 in. (35.5 cm – 51 cm) in Width (increments of 2 in. (5 cm)).



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

Comfort Unite Back Supports

Comfort Unite 1 Back Support

U1-BS12W12L-E
U1-BS12W14L-E
U1-BS12W16L-E
U1-BS14W12L-E
U1-BS14W14L-E
U1-BS14W16L-E
U1-BS14W18L-E
U1-BS16W12L-E
U1-BS16W14L-E
U1-BS16W16L-E
U1-BS16W18L-E
U1-BS16W20L-E
U1-BS18W12L-E
U1-BS18W14L-E
U1-BS18W16L-E
U1-BS18W18L-E
U1-BS18W20L-E
U1-BS20W14L-E
U1-BS20W16L-E
U1-BS20W18L-E
U1-BS20W20L-E

Comfort Unite 2 Back Support

U2-BS14W14L-E
U2-BS14W16L-E
U2-BS14W18L-E
U2-BS14W20L-E
U2-BS16W14L-E
U2-BS16W16L-E
U2-BS16W18L-E
U2-BS16W20L-E
U2-BS18W14L-E
U2-BS18W16L-E
U2-BS18W18L-E
U2-BS18W20L-E
U2-BS20W14L-E
U2-BS20W16L-E
U2-BS20W18L-E
U2-BS20W20L-E

Comfort Unite 3 Back Support

U3-BS14W14L-E
U3-BS14W16L-E
U3-BS14W18L-E
U3-BS14W20L-E
U3-BS16W14L-E
U3-BS16W16L-E
U3-BS16W18L-E
U3-BS16W20L-E
U3-BS18W14L-E
U3-BS18W16L-E
U3-BS18W18L-E
U3-BS18W20L-E
U3-BS20W14L-E
U3-BS20W16L-E
U3-BS20W18L-E
U3-BS20W20L-E
U3R-BS16W16L-E
U3R-BS16W18L-E
U3R-BS16W20L-E
U3R-BS18W16L-E
U3R-BS18W18L-E
U3R-BS18W20L-E
U3R-BS20W16L-E
U3R-BS20W18L-E
U3R-BS20W20L-E

Comfort Embrace Back Support

E-BS10W14L-E
E-BS12W14L-E
E-BS14W16L-E
E-BS14W18L-E

Comfort Relief Back Support

R-BS14W10L-E
R-BS14W12L-E
R-BS14W14L-E
R-BS14W16L-E
R-BS14W18L-E
R-BS14W20L-E
R-BS16W10L-E
R-BS16W12L-E
R-BS16W14L-E
R-BS16W16L-E
R-BS16W18L-E
R-BS16W20L-E
R-BS18W10L-E
R-BS18W12L-E
R-BS18W14L-E
R-BS18W16L-E
R-BS18W18L-E
R-BS18W20L-E
R-BS20W16L-E
R-BS20W18L-E
R-BS20W20L-E



Basic UDI: 0194637CBSJS

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: Annex IV EU DECLARATION OF CONFORMITY

Standards: Conformity to the general safety and performance requirements have been demonstrated by using the following standards:

ISO 14971:2019	ISO 10993-23: 2021
ISO 16840-3: 2022	ISO 7176-19: 2022
ISO 16840-4: 2009	ISO 7176-8: 2014
ISO 16840-6: 2015	ANSI/RESNA WC-4:2017
ISO 16840-10: 2022	ISTA - 3A: 2018
BS EN ISO 10993-5: 2009	BS EN 12183: 2022
BS EN ISO 10993-10: 2021	BS EN ISO 21856: 2022

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01 December 2024

On behalf of The Comfort Companies, LLC

Seth Flaaten
Quality Assurance/Regulatory Compliance Manager