



DECLARATION OF CONFORMITY

according to Annex IV of the Medical Device Regulation (MDR) 2017/745



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Intended Use

The products Nick, Noah, Galileo, Sunny/ -Swing and Mika (see table 1, page 2 for specific product names) are adjustable seat base frames applied in general areas life, in the care sector and in the domestic area. They are designed to be combined with seat shells or seating systems to support therapeutic applications for people with moderate to severe sitting malpositions and/or sitting posture instabilities, thereby enabling pain-free sitting in a physiologically correct posture.

We declare under our sole responsibility that the medical devices in table 1 (risk class I according to Annex VIII, rule 1 and 13) comply with the requirements of Regulation (EU) 2017/745 and EU Directive 2006/42/EC. The conformity assessment according to Regulation (EU) 2017/745 is based on Annex IX.

This declaration of conformity is valid until 31 December 2024.

Schönau, 2 January 2024

(Dieter Frank, General Manager)

Table 1 All products of the Underframes product group incl. article numbers and sizes

Basic UDI	Product name	Article number	Trade name	UDI-DI
++G073UNDERFRAMESQX	Nick hi-lo base	1021899	Nick Hi-Lo Base Size 1	G07310218990
		1021900	Nick Hi-Lo Base Size 2	G07310219000
		1021901	Nick Hi-Lo Base Size 3	G07310219010
	Noah Hi-Lo Base	1025921	Noah Hi-Lo Base Size Mini	G07310259210
		1020544	Noah Hi-Lo Base Size 1	G07310205440
		1020924	Noah Hi-Lo Base Size 2	G07310209240
	Galileo Mobility Base	1016354	Galileo Mobility Base Size Mini	G07310163540
		1023888	Galileo Mobility Base Size 0	G07310238880
		1023889	Galileo Mobility Base Size 1	G07310238890
		1023890	Galileo Mobility Base Size 2k	G07310238900
		1023891	Galileo Mobility Base Size 2l	G07310238910
		1023892	Galileo Mobility Base Size 3	G07310238920
		1023893	Galileo Mobility Base Size 4	G07310238930
		1023894	Galileo Mobility Base Size 5	G07310238940
		1023896	Galileo Mobility Base Size 6	G07310238960
	Mika Mobility Base	1023900	Mika Mobility Base Size 0	G07310239000
		1023902	Mika Mobility Base Size 1	G07310239010
		1023901	Mika Mobility Base Size 2	G07310239020
		1023903	Mika Mobility Base Size 3	G07310239030
	Sunny Mobility Base	1023895	Sunny Mobility Base Size 2	G07310238950
		1023897	Sunny Mobility Base Size 3	G07310238970
		1023898	Sunny Mobility Base Size 2	G07310238980
		1023899	Sunny Mobility Base Size 3	G07310238990