



DECLARATION OF CONFORMITY

in accordance with Annex IV of the Medical Devices Regulation (MDR) 2017/745

Rehatec® GmbH

DE-MF-000006549

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intended use

The Upright Standers / Mobile Standers (see Table 1 on page 2 for product names) is designed for patients with standing impairments to maintain as physiological a standing position as possible for a few hours per day and to ensure stable standing. It enables the positive effects of a standing body position to be achieved. The standing device (see table for product names) can be equipped with a gas pressure spring or an electric motor to make it easier for the patient to stand up.

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

This declaration of conformity is valid until 31.12.2025

Schönau, 02.01.2025

A handwritten signature in blue ink, appearing to read "Dieter Frank", written in a cursive style.

(Dieter Frank, CEO)

Table 1 All products in the product group Standing with item numbers and sizes

Basis-UDI	Product name	Code	Trade name	UDI-DI
++G073STANDINGCT	Heidelberg Upright and Supine Stander Lasse	1018442	Heidelberg Upright and Supine Stander Lasse Size Mini	G07310184420
		1007212	Heidelberg Upright and Supine Stander Lasse Size 1	G07310072120
		1007955	Heidelberg Upright and Supine Stander Lasse Size 2	G07310079550
		1020435	Heidelberg Upright and Supine Stander Lasse Size 3G	G07310204350
		1007563	Heidelberg Upright and Supine Stander Lasse Size 3	G07310075630
		1007005	Heidelberg Upright and Supine Stander Lasse Size 4	G07310070050
		1018966	Heidelberg Upright and Supine Stander Lasse Size 5	G07310189660
	Biometric Standing System Da Vinci	1023802	Biometric Standing System Da Vinci Size 1	G07310238020
		1023801	Biometric Standing System Da Vinci Size 2	G07310238010
	Heidelberg Upright Stander Standard	1004287	Heidelberg Upright Stander Standard Size 1	G07310042870
		1017707	Heidelberg Upright Stander Standard Size 2	G07310177070
		1017350	Heidelberg Upright Stander Standard Size 3	G07310173500
	Heidelberg Upright Stander Impuls	1023677	Heidelberg Upright Stander Impuls Size 1	G07310236770
		1023647	Heidelberg Upright Stander Impuls Size 2	G07310236470
	Heidelberg Upright Stander Jumbo	1002015	Heidelberg Upright Stander Jumbo Size 1	G07310020150
		1026211	Heidelberg Upright Stander Jumbo Size 2	G07310262110
		1018357	Heidelberg Upright Stander Jumbo for hipknee-ankle-foot orthosis Size 1	G07310183570
		1026507	Heidelberg Upright Stander Jumbo for hipknee-ankle-foot orthosis Size 2	G07310265070
	Heidelberg Upright Stander Benni	1022832	Heidelberg Upright Stander Benni Light Size 1	G07310228320
		1022840	Heidelberg Upright Stander Benni Light Size 2	G07310228400
		1022159	Heidelberg Upright Stander Benni Size 1	G07310221590
		1021714	Heidelberg Upright Stander Benni Size 2	G07310217140
	Heidelberg Upright Stander Speedy	1020477	Heidelberg Upright Stander Speedy Size 0	G07310204770
		1003693	Heidelberg Upright Stander Speedy Size 1	G07310036930
		1003695	Heidelberg Upright Stander Speedy Size 2	G07310036950
		1003694	Heidelberg Upright Stander Speedy Size 3	G07310036940