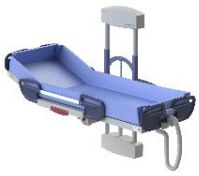
lopital®
If caregivers have a choice

Manufacturer's EU Declaration of Conformity

CE marking in accordance with the REGULATION (EU) 2017/745 on Medical Devices (MDR)

This EU Declaration of Conformity is issued under the sole responsibility of Lopital Nederland B.V. We hereby declare that each medical device covered by this Declaration conforms to the applicable requirements of REGULATION (EU) 2017/745 on medical devices (MDR).

Manufacturers Name:	Lopital Nederland B.V.
Manufacturers Adress:	Laarakkerweg 9, 5061 JR, Oisterwijk The Netherlands
Manufacturers SRN: (Single Registration Number)	NL-MF-000004372



Brand Name:	Lopital	
Medical Device:	Sirocco Basic shower stretcher	Sirocco Deluxe shower stretcher
Model Number:	61002500	61002510
Basic UDI:	8720256103561610025OOL7	872025610357861002510S8
Intended purpose:	Intended to support the safe and ergonomic washing, showering, and care of clients with limited mobility by trained caregivers in healthcare environments.	
Classification:	Class I according to Rule 13, Annex VIII of REGULATION (EU) 2017/745 on Medical Devices	
Conforms to regulation:	REGULATION (EU) 2017/745 on Medical Devices	

No Common Specifications (CS) have been applied.

Additional information:

Standards applied:	NEN-EN-ISO 14971:2019 ISO 17966:2016
The products in this DoC have been tested and evaluated in accordance with the following standards:	EN 60601-1-2 (2015)+A1(2021) NEN-EN-IEC 62366-1:2015
The products in this DoC have been designed and manufactured under a certified quality management system in accordance with:	UNI-CEI-ISO 13485:2021

Signed for and on behalf of Lopital Nederland B.V.:

Signature:	Date:	Place:
Wojciuk	*14-07-2026*	Oisterwijk, Netherlands
Patrycja Wojciuk, Manager Quality and Regulatory	*dd-mm-yyyy*	City, land

Document Number: DOC2500-2024-04