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

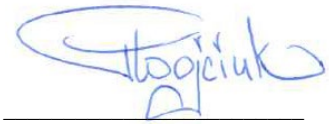
Brand Name:	Lopital		
Medical Device:	Lotus active standup aid	Lotus Compact active standup aid	Lotus XL active standup aid
Model Number:	59008200	59008250	59008270
Basic UDI:	872025610361559008200PZ	872025610332559008250NL	872025610364659008270U4
Intended purpose:	Intended to support safe and efficient short transfers for individuals who can stand independently but have difficulty walking.		
Classification:	Class I according to Rule 1, 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
The products in this DoC have been tested and evaluated in accordance with the following standards:	ISO 10535:2021 (corrigendum 2023-11) NEN-EN-IEC 62366-1:2015/A1:2020
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:
	*12-08-2026*	Oisterwijk, Netherlands
Patrycja Wojciuk, Manager Quality and Regulatory	*dd-mm-yyyy*	City, land

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