Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation (EU) 2017/745

Manufacturer's name:	Lopital Nederland B.V.
Manufacturer's Adress:	Laarakkerweg 9, 5061 JR, Oisterwijk The Netherlands
Manufacturer's SRN (Single Registration Number):	NL-MF-000004372
Brand Name:	Lopital
	
Medical device:	Reflex
Model number(s):	51005600 & 51005605
Device Description:	Mobile Shower-Toiletchair with electrically adjustable height and inclination
Basic UDI-DI:	872025610300451005600CA & 872025610301151005605BC
Classification:	Class I
Conforms to regulation:	Medical Device Regulation (EU) 2017/745
Standards applied:	NEN-EN-ISO 14971:2019
The product has been tested and evaluated in accordance with the following standards:	ISO 17966:2016 IEC 62366:2007 IEC 60529:2019 IEC 60601-1:2005 + A1:2012 IEC 60601-1-2:2007 IEC 60601-1-6:2010 CAN/CSA-C22.2 No. 60601-1:14 ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012
The product has been designed and manufactured under a certified quality management system in accordance with:	UNI-CEI-EN-ISO 13485:2016

This declaration of conformity is issued under the sole responsibility of Lopital. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

Signature:	Date:	Place:
	12-12-2024	Oisterwijk
Jan Van Megen, CEO	dd-mm-yyyy	

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