

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 Address: Laarakkerweg 9, 5061 JR, Oisterwijk
The Netherlands
Manufacturers SRN: NL-MF-000004372
(Single Registration Number)



Brand Name:	Lopital	
Medical Device:	Reflex 5600 shower toilet chair	Reflex 5605 shower toilet chair
Model Number:	51005600	51005605
Basic UDI:	872025610300451005600CA	872025610301151005605BC

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:

IEC 62366:2007
IEC 60529:2019
IEC 60601-1:2005 + C1:2006 + C2:2007 +A1:2012
IEC 60601-1-6:2010 (third edition) +A1:2013
CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI
ES60601-1:2005/A2:2010
IEC 60601-1-2:2007

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:



16-07-2026

Oisterwijk, Netherlands

Patrycja Wojciuk, Manager Quality and
Regulatory

dd-mm-yyyy

City, land