

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:	Elexo shower toilet chair	Elexo XXL shower toilet chair
Model Number:	51005500	51005300
Basic UDI:	872025610302851005500GT	872025610316551005300JX
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	
<i>No Common Specifications (CS) have been applied.</i>		

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:

NEN-EN-IEC 60529:1992/A2:2013/C1:2019
NEN-EN-IEC 62366-1:2015/A1:2020
IEC 60601-1:2005+C1:2006+C2:2007+A1:2012
IEC 60601-1-2:2007
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

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: _____



14-07-2026

Oisterwijk, Netherlands

Patrycja Wojciuk, Manager Quality and
Regulatory

dd-mm-yyyy

City, land