

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:	Timo 6020 shower chair	Timo 6021 shower toilet chair	Timo 6025 shower chair	Timo 6030 shower chair	Timo 6034 shower chair	Timo 6035 shower toilet chair
Model Number:	54006020	54006021	54006025	54006030	54006034	54006035
Basic UDI:	8720256103 0735400602 0JY	8720256103 0805400602 1HS	8720256103 0975400602 5PY	8720256103 1035400603 ODP	8720256103 4795400603 4TH	8720256103 1105400603 5CR

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 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
 ISO 17966:2016

The products in this DoC have been tested and evaluated in accordance with the following standards: 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:
 Oisterwijk, Netherlands



Patrycja Wojciuk, Manager Quality and Regulatory

 dd-mm-yyyy

 City, land