

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 Address: Laarakkerweg 9, 5061 JR, Oisterwijk
The Netherlands

Manufacturer's SRN
(Single Registration Number): NL-MF-000004372

Brand Name: Lopital



Medical device: Timo 6005
Model number(s): 54006005
Device Description: Shower stool
Basic UDI-DI: 872025610367754006005TS

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 62366-1:2015+A1:2020

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:



Jan Van Megen, CEO

Date:

21-01-2026

dd-mm-yyyy

Place:

Oisterwijk