

Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

Brand name: Lopital
Medical device: Nemo
Device description: Mobile shower-/toilet chair with inclination
Models: 51005100
Classification: Class I
Basic UDI-DI: 872025610304251005100DP
Conforms to regulation: Medical Device Regulation (EU) 2017/745



Standards applied: NEN-EN-ISO 14971:2019 | *Medical devices-Application of risk management to medical devices*
NEN-EN 12182:2012 | *Assistive product for persons with disability-General requirements and test methods*
ISO 17966:2016 | *Assistive products for personal hygiene that support users-Requirements and test methods*
IEC 62366:2007 | *Medical devices - Application of usability engineering to medical devices*
UNI-CEI-EN-ISO 13485:2016 | *Medical devices-Quality management systems-Requirements for regulatory purposes*
NEN-EN-ISO 9001:2015 | *Quality management systems - Requirements*
NEN-EN-ISO 14001:2015 | *Environmental management systems - Requirements with guidance for use*

Certificate/report no.: Certificate:
Reports:

Authorised signatory, Cees van Dam, director:

Signature:



Date:

2021-05-03

Place:

Oisterwijk