

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: Vienna Deluxe wall-mounted electrical dressing table
Model Number: 65005030
Basic UDI: 872025610360861005030P2
Intended purpose: Intended to support the safe and ergonomic 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 Product has 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
EN 60601-1-2:2015/A1:2021

The product has 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