# Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation (EU) 2017/745

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|---|---|
| **Manufacturer's name:** | Lopital Nederland B.V. |
| **Manufacturer's Adress:** | Laarakkerweg 9, 5061 JR, Oisterwijk<br>The Netherlands |
| **Manufacturer's SRN**<br>(Single Registration Number): | NL-MF-000004372 |
| **Brand Name:** | Lopital |
| |  |
| **Medical device:** | Flexo |
| **Model number(s):** | 51005199 |
| **Device Description:** | Mobile Shower-Toiletchair with hydraulically adjustable height |
| **Basic UDI-DI:** | 872025610303551005199GC |
| **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<br>EN-IEC 62366-1:2015 |
| 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: | Date: | Place: |
|---|---|---|
| | 12-12-2024 | Oisterwijk |
| Jan Van Megen, CEO | dd-mm-yyyy | |

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