


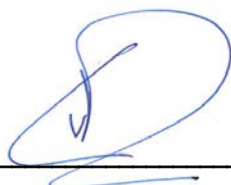
## Manufacturer's Declaration of Conformity

CE marking in accordance with the Medical Device Regulation

<b>Brand name:</b>	Lopital	
<b>Medical device:</b>	Reflex	
<b>Device description:</b>	Mobile shower-/toilet chair with electrically adjustable height and inclination	
<b>Models:</b>	51005600 & 51005605	
<b>Classification:</b>	Class I	
<b>Basic UDI-DI:</b>	872025610300451005600CA & 872025610301151005605BC	
<b>Conforms to regulation:</b>	Medical Device Regulation (EU) 2017/745	
<b>Standards applied:</b>	NEN-EN-ISO 14971:2019   <i>Medical devices-Application of risk management to medical devices</i> NEN-EN 12182:2012   <i>Assistive product for persons with disability-General requirements and test methods</i> ISO 17966:2016   <i>Assistive products for personal hygiene that support users -Requirements and test methods</i> IEC 60529:2019   <i>Degrees of protection provided by enclosures (IP Code)</i> IEC 60601-1:2005 + A1:2012   <i>Medical electrical equipment - Part 1: General requirements for basic safety and essential performance</i> IEC 60601-1-2:2007   <i>Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests</i> IEC 60601-1-6:2010   <i>Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability</i> IEC 62366-1:2007   <i>Medical devices - Part 1: Application of usability engineering to medical devices</i> CAN/CSA-C22.2 No. 60601-1:14   <i>Medical electrical equipment - part 1: General requirements for basic safety and essential performance</i> ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012   <i>General requirements for basic safety and essential performance</i> UNI-CEI-EN-ISO 13485:2016   <i>Medical devices-Quality management systems-Requirements for regulatory purposes</i> NEN-EN-ISO 9001:2015   <i>Quality management systems - Requirements</i> NEN-EN-ISO 14001:2015   <i>Environmental management systems - Requirements with guidance for use</i>	
<b>Certificate/report no.:</b>	Certificate: NL-36634 Reports: 2174112.50 (A,B,C,D), 2174112.0501-EMC	

Authorised signatory, Cees van Dam, director:

Signature:



Date:

2021-05-03

Place:

Oisterwijk