



**Manufacturer's Declaration of Conformity**

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

<b>Manufacturer's name:</b>	Lopital Nederland B.V.
<b>Manufacturer's Address:</b>	Laarakkerweg 9, 5061 JR, Oisterwijk The Netherlands
<b>Manufacturer's SRN</b> (Single Registration Number):	NL-MF-000004372
<b>Brand Name:</b>	Lopital 
<b>Medical device:</b>	Lotus, Lotus Compact & Lotus XL
<b>Model number(s):</b>	59008200, 59008250 & 59008270
<b>Device Description:</b>	Active Standup Aid
<b>Basic UDI-DI:</b>	872025610361559008200PZ, 872025610332559008250NL & 872025610364659008270U4
<b>Classification:</b>	Class I
<b>Conforms to regulation:</b>	Medical Device Regulation (EU) 2017/745
<b>Standards applied:</b>	NEN-EN-ISO 14971:2019
The product has been tested and evaluated in accordance with the following standards:	ISO 10535:2021 (corrigendum 2023-11) 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:	Date:	Place:
	04-06-2026	Oisterwijk
Patrycja Wojciuk, Manager quality & Regulatory	dd-mm-yyyy	