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## Manufacturer's Declaration of Conformity

(CE marking in accordance with the Medical Device Regulation)

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Brand name:	Lopital	
Medical device:	Lotus & Lotus compact	
Device description:	Standing aid	
Models:	59008200 & 59008250	
Classification:	Class I	
Basic UDI-DI:	872025610361559008200PZ & 872025610332559008250NG	
Conforms to regulation:	Medical Device Regulation (EU) 2017/745	
Standards applied:	NEN-EN-ISO 14971:2019   <i>Medical devices-Application of risk management to medical devices</i> ISO 10535:2021   <i>Hoists for the transfer of disabled persons – Requirements and test methods</i> IEC 62366: 2015   <i>Medical devices - Application of usability engineering to medical devices</i> <hr/> 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>	
Certificate/report no.:	Certificate:	
	Reports:	

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Authorised signatory, Jan van Megen, CEO:

Signature:



Date:

2023-11-22

Place:

Oisterwijk