

Manufacturer's Declaration of Conformity

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

Manufacturer's name: Manufacturer's Adress:	Lopital Nederland B.V. Laarakkerweg 9, 5061 JR, Oisterwi The Netherlands	ik
Manufacturer's SRN (Single Registration Number):	NL-MF-000004372	
Brand Name:	Lopital	
Medical device:	Sirocco basic fixed height	
Model number(s): Device Description:	61002505 Wall mounted Shower Stretcher	
Basic UDI-DI:	872025610363961002505QH	
Classification:	Class I	
Conforms to regulation:	Medical Device Regulation (EU) 20	17/745
Standards applied:	NEN-EN-ISO 14971:2019	
The product has been tested and evaluated in accordance with the following standards:	ISO 17966:2016 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 u device(s) specified above meet the prov	nder the sole responsibility of Lopital. We ision of the Regulation (EU) MDR 2017/7	e hereby declare that the medical 145 for medical devices.
Signature:	Date:	Place:
NVM	12-12-2024	Oisterwijk

dd-mm-yyyy

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Jan Van Megen, CEO