

EU Declaration of Conformity (DoC)

NOTICE: Sections bracketed with three plus signs (+++) may not be changed or removed without approval from a Quality Director or designee within the Entity and/or function (do not delete the text in this header).

Liko M220, Liko M230 & Uno 102 EE	Document Number: NPD39186; Version: 5.0	
Manufacturer Name and Address: Liko AB, Nedre vägen 100, 975 92 Luleå, Sweden, +46 (0)920 474700		
Manufacturer Single Registration Number (SRN): SE-MF-000001404		
Authorised Representative Name and Address: Not Applicable, Registered place of business is within European union		
Authorised Representative Single Registration Number (SRN): Not Applicable		
+++ We as Manufacturer declare, under our sole responsibility, that the product(s) listed below conform to the applicable provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices, and the following Directive(s), Regulation(s) and Common Specification(s). +++		
Other relevant Directives, Regulations and Union Legislations that the device is in conformity with: <ul style="list-style-type: none">• The Directive 2011/65/EU (including amendment 2015/863) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)		
Common Specifications Applied: Not Applicable		
Product/Trade Name and Product Code or REF. number: Liko M220, Liko M230 & Uno 102 EE		
Reference Number	Description	Product Basic UDI-DI Number:
2010004	UNO 102 EE	0887761GMN000034U5
2050010	LIKO M220	
2050015	LIKO M230	
Intended Purpose/Use: <p><i>Uno</i> is intended mainly for use in Post-Acute Care facilities like nursing homes and other care homes in the most common lifting situations, for instance, transfers between bed and wheelchair, to and from toilet and for lifting to and from the floor.</p> <p><i>M220 M230</i> models are excellent aids for daily transfers of adults and children, for instance, for transfers to and from a wheelchair, toilet and floor.</p> <p>It is intended for use in following environments: Health care, Intensive care, Emergency ward, Rehabilitation, and Habilitation.</p>		
Device Risk Class: Class I		
MDR EU Certificate(s) No.: Not Applicable		
Conformity Assessment Description/Annexes: Annex II and Annex III		

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Notified Body Name and Address: Not Applicable as it is class I Product

Notified Body Identification Number: Not Applicable as it is class I Product

+++ This Declaration is made on the following basis:

- **For devices with a MDR EU Certificate issued by a Notified Body:**
 - The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.
 - The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.
- **For Class I devices (*that are non-sterile, have no measurement function or are not reusable surgical instruments*) the DoC declares conformity to the product lots released after the date of signature.**
- **Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).**
- **Additional information may be attached/appended to this template, such as common specifications, compliance to other union regulations/registrations, product code list or any other supporting information. +++**

Authorised Signatory:

Name and Title:	Sofie Nybom
Function:	QMR
Place of Issue:	Luleå, Sweden
Date of Issue:	27-NOV-2023
Signature:	