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).

Sabina II	**Document Number:** NPD39183; **Version:** 5.0

Manufacturer Name and Address: Liko AB and Nedre vagen 100, 975 92 Lulea, Sweden

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:

- 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: Sabina II EE

Reference Number	Description	Product Basic UDI-DI Number:
2020003 2027011	SABINA II EE HEEL SUPPORT SABINA II	0887761GMN000037UB
2027002 2027003 2027006 2027007	SABINA II 350 - SLINGBAR SABINA II COMFORT SLINGBAR SABINA SEATSTRAP SLINGBAR SABINA II SEATSTR. SLINGBAR	0887761GMN000036U9
3591115 3591134 3591135 3591136 3591137 3593115 3593116 3595414 3595415 3595416 3595417 3691107 20290022 35911915-4 35911916-4	SABINA SEATSTRAP 91 PES SUPPORTVEST with padding, S SUPPORTVEST M CORDUROY SUPPORTVEST L CORDUROY SUPPORTVEST XL CORDUROY SAFETYVEST 93 PES M SAFETYVEST 93 PES L COMFORTVEST 95 PL.NET S COMFORTVEST 95 PL.NET M COMFORTVEST 95 PL.NET L COMFORTVEST 95 PL.NET XL EXTENSION BELT SUPPORTVEST STRAP F LEG SUPPORT, SA SOLO SUPPORTVEST M BOX 20 SOLO SUPPORTVEST L BOX 20	0887761GMN000038UD

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Intended Purpose/Use:

Sabina II EE sit-to-stand lift is used to assist people who have difficulty raising from a sitting to a standing position, for example from a wheelchair, chair, bed or when using the toilet

The ComfortVest is designed to support behind the patient's back and outside of the arms in combination with the Comfort SlingBar and Sabina sit-to-stand lift.

The Solo SupportVest is used in combination with the Sabina™ sit-to-stand lift to assist lifting of patients from a seated to a standing position. The Solo SupportVest lifts behind the back and under the arms. It is suitable for patients who have to be helped to a standing position but are able to stand steadily on their own once they are up.

Intended for use in following environments: Health care, Intensive care, Emergency ward, Rehabilitation, and Habilitation.

Device Risk Class: Class I

MDR EU Certificate(s) No.: Not Applicable

Conformity Assessment Description/Annexes: Annex II and III

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. +++**

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