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).

FlexoStretch & UltraStretch	**Document Number:** NPD39188; **Version**: 3.0

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

Not Applicable

Common Specifications Applied: Not Applicable

Product/Trade Name and Product Code or REF. number: FlexoStretch and UltraStretch

Reference Number	Description	UDI
3156057	FLEXOSTRETCH	0887761GMN000036U9
3156058	ULTRASTRETCH	
3684105	LIFTSHEET XL, REGULAR	0887761GMN000038UD
3684106	LIFTSHEET XL, TALL	

Intended Purpose/Use:

Flexotsretch accessory is intended for lifting and transferring patients in a horizontal supine position. The load-carrying part consists of an entire LiftSheet™ or, alternatively, five LiftStraps. The width of the stretcher can be adjusted between 70 and 95 cm, by pulling the lift arms either out or in. Flexostretch accessory is equipped with a Stretch Leveler to make it easy to control the center of gravity during the lift.

UltraStretch is intended for lifting and transfer of heavy patients in a fully supine position. UltraStretch is used in combination with Liko's lift System.

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

Device Risk Class: Class I

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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. +++**

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