

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: <p>Flexostretch 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.</p> <p>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.</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		

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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: <ul style="list-style-type: none">• For devices with a MDR EU Certificate issued by a Notified Body:<ul style="list-style-type: none">○ 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 (<i>that are non-sterile, have no measurement function or are not reusable surgical instruments</i>) 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:	