

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).

OctoStretch	Document Number: NPD39184; 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: OctoStretch		
REF. number	Description	UDI
3156056	OCTOSTRETCH WITH LEV	0887761GMN000038UD
3683105	LIFTSHEET OCTO, POLY M	
3683106	LIFTSHEET OCTO, POLY L	
3683905	SOLO OCTO LIFTSHEET M	
3683905-4	SOLO OCTO LIFTSHEET M	
3683906	SOLO OCTO LIFTSHEET L	
3683906-4	SOLO OCTO LIFTSHEET L	
Intended Purpose/Use: OctoStretch is an accessory intended for lifting and transferring patients in a horizontal position in cases where a particularly flat underlying lifting surface is not required. It is 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 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:	