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).

Universal Slings	**Document Number:** NPD39185; **Version:** 4.0

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: Universal Slings M-Slim, S, M, L, XL

Reference Number	Description	Product Basic UDI-DI Number:
1. 35000111	1. UNIVERSALSLING, M-SLIM	0887761GMN000038UD
2. 35000114	2. UNIVERSALSLING, S	
3. 35000115	3. UNIVERSALSLING, M	
4. 35000116	4. UNIVERSALSLING, L	
5. 35000117	5. UNIVERSALSLING, XL	
6. 35000304	6. UNIVERSALSLING, S	
7. 35000305	7. UNIVERSALSLING, M	
8. 35000306	8. UNIVERSALSLING, L	
9. 35000311	9. UNIVERSALSLING, M-SLIM	
10. 35000314	10. UNIVERSALSLING, S	
11. 35000315	11. UNIVERSALSLING, M	
12. 35000316	12. UNIVERSALSLING, L	
13. 35000317	13. UNIVERSALSLING, XL	
14. 35000404	14. UNIVERSALSLING, XL	
15. 35000405	15. UNIVERSALSLING 000 PL.NET S	
16. 35000406	16. UNIVERSALSLING 000 PL. NETM	
17. 35000407	17. UNIVERSALSLING 000 PL.NET L	
18. 35000115US	18. UNIVERSALSLING, M	
19. 35000116US	19. UNIVERSALSLING, L	
20. 35000117US	20. UNIVERSALSLING, XL	

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).

21. 35000304US	21. UNIVERSALSLING, S	
22. 35000305US	22. UNIVERSALSLING, M	
23. 35000306US	23. UNIVERSALSLING, L	
24. 35000311US	24. UNIVERSALSLING, M-SLIM	
25. 35000314US	25. UNIVERSALSLING, S	
26. 35000315US	26. UNIVERSALSLING, M	
27. 35000316US	27. UNIVERSALSLING, L	
28. 35000317US	28. UNIVERSALSLING,XL	

Intended Purpose/Use:

Universal Sling, mod 000 used as a basic model which is designed to adapt to the patient without individual adjustments. The Universal Sling provides an upright sitting posture and supports the entire back up to the neck. Used for lifting to/from a Sitting Position, lifting to/from the Bed. The polyester fabric is durable and has low friction making the sling easy to apply and easy to remove. The reinforced leg supports provides high comfort, equalizes pressure, and prevents the sling from creasing under the thighs.

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

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. +++**

Authorised Signatory:

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).

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