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).

Amputee Sling	**Document Number:** NPD39192; **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: Amputee Sling

Reference Number	Description	UDI
3575114	AMPUTEE SLING HB 75 PES S	0887761GMN000038UD
3575115	AMPUTEE SLING HB 75 PES M	
3575116	AMPUTEE SLING HB 75 PES L	
3575117	AMPUTEE SLING HB 75 PES XL	
3575315	AMPUTEE SLING HB 75 PES MESH M	

Intended Purpose/Use:

Amputee Slings is a Safe, easy to use sling that has been specially designed as an aid to lifting patients with double sided leg amputations. It is also recommended to use Amputee sling for patients who are not amputees, but who tend to slide out of similar type of slings. Amputee may be appropriate for other patients, such as single sided amputees.

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

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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: