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).

ComfortSling	**Document Number:** NPD34684; **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: ComfortSling Plus

Reference Number	Description	Product Basic UDI-DI Number:
35300304	ComfortSling Plus 300, S	0887761GMN000038UD
35300305	ComfortSling Plus 300, Mesh M	
35300306	ComfortSling Plus, 300 Mesh L	
35300307	ComfortSling Plus 300, Mesh XL	
35350304	ComfortSling Plus 350, S	
35350305	ComfortSling Plus 350 Mesh M	
35350306	ComfortSling Plus 350 Mesh L	
35350307	ComfortSling Plus 350 Mesh XL	

Intended Purpose/Use:

Liko ComfortSling Plus provides a comfortable sitting position and safe patient transfer between, e.g. the bed and wheelchair.

ComfortSling Plus will be suitable for patients who are especially sensitive due to muscle or joint pain. ComfortSling Plus will also often suitable even for amputees because it will provide support under the entire sitting surface.

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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 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: