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).

Reposheets	**Document Number:** NPD39196; **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: Reposheets

Reference Number	Description	Product Basic UDI-DI Number:
3687301	REPOSHEET PES MESH REGULAR	0887761GMN000038UD
3687302	REPOSHEET PES MESH ULTRA	
3687701	REPOSHEET ORIG, REG	
3687701US	REPOSHEET ORIG, REG	
3687702	REPOSHEET ORIG ULTRA	
36871003	SOLO REPOSHEET, SHORT	
36871003-2	SOLO REPOSHEET, SHORT, BOX 20	
36871004	SOLO REPOSHEET GENEROUS	
36871004-8	SOLO REPOSHEET GENEROUS 8 PCS	

Intended Purpose/Use:

Repo Sheet Original has been specially developed by Liko to facilitate repositioning of the patient in bed. It is ideal for moving the patient higher up in the bed and turning the patient with the aid of a lift, with minimal physical effort by the caregiver.
The material polyester/cotton is recommended which has a soft and comfortable surface.
Solo Repo Sheet Generous and short:
Solo Repo Sheet is to facilitate transfers of a patient in bed.

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It is an excellent aid for repositioning further up in bed and during turning in beds using a lift and with minimal body strain for the caregivers with minimal physical effort by the caregiver It is intended for single patient use. 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: