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).

Highback Sling	**Document Number:** NPD24281; **Version** 5.0

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: Highback Sling

Reference Number	Description	Product Basic UDI-DI Number:
35200103	ORIG HB SLING 200 PES XS	0887761GMN000038UD
35200104	ORIG HB SLING 200 PES S	
35200105	ORIG HB SLING PES M	
35200106	ORIG HB SLING 200 PES L	
35200107	ORIG HB SLING 200 PES XL	
35200113	ORIG HB SLING 200 PES XS	
35200114	ORIG HB SLING 200 REINF PES S	
35200115	ORIG HB SLING,M,REINF,POL	
35200116	ORIG HB SLING 200 PES L	
35200117	ORIG HB SLING 200 PES XL	
35200303	ORIG HB SLING 200 MESH XS	
35200304	ORIG HB SLING 200 POL NET S	
35200305	ORIG HB SLING 200 POL NET M	
35200306	ORIG HB SLING 200 POL NET L	
35200307	ORIG HB SLING 200 MESH XL	

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35200313	ORIG HB SLING 200 MESH XS	
35200314	ORIG HB SLING 200 POL NET S	
35200315	MS ORIG HB REINF POL.NETM	
35200316	MS ORIG HB REINF POL.NETL	
35200317	ORIG HB SLING 200 MESH XL	
35200403	ORIG HB SLING 200 PLNET XS	
35200404	ORIG HB SLING 200 PLNET S	
35200405	ORIG.HB SLING,M, PL NET	
35200406	ORIG HB SLING 200 PLNET L	
35200407	ORIGINAL HB SLING 200 PLNET XL	
35200418	ORIG HB SLING 200 PLNET XXL	
35210115	ORIG HB SLING 210 REINF MS	
35210305	ORIG HB SLING 200 POL NET MS	
35210315	ORIG HB SLING 210 MESH MS	
35210405	ORIG HB SLING 210 PLNET MS	
35200304US	ORIG HB SLING 200 POL NET S	
35200305US	ORIG HB SLING 200 POL NET M	
35200306US	ORIG HB SLING 200 POL NET L	
35200314US	ORIG HB SLING 200 POL NET S	
35200315US	MS ORIG HB REINF POL.NETM	
35200316US	MS ORIG HB REINF POL.NETL	
35200404US	ORIG HB SLING 200 PLNET S US	
35200405US	ORIG.HB SLING,M, PL NET	
35200406US	ORIG HB SLING 200 PLNET L	
35200407US	ORIGINAL HB SLING 200 PLNET XL	
35210115US	ORIG HB SLING 210 REINF MS	
35210305US	ORIG HB SLING 200 POL NET MS	
3525911-2	SOLO HBACK SLING, MS BOX OF 10	
3525915-2	SOLO HBACK SLING, M, BOX OF 10	
3525916-2	SOLO HBACK SLING, L, BOX OF 10	
3525917-2	SOLO HBACK SLING, XL, BOX OF 4	
3526111	SOFT ORIGINAL HIGH BACK M-SLIM	
3526115	SOFT ORIGINAL HIGH BACK,M	
3526116	SOFT ORIGINAL HIGH BACK,L	
3526117	SOFT ORIGINAL HIGH BACK, XL	
3526118	SOFT ORIG.HB SLING 26 PES XXL	

Intended Purpose/Use:

HighBack Slings of all variants and models intended for most common transfers, for instance, transfers between bed and wheelchair, to and from toilet and bath-tub, or for lifting from and to the floor.

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

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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: