

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).

HandyBelt	Document Number: NPD39199; 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: Handy Belt													
<table border="1" style="width: 100%; border-collapse: collapse;"><thead><tr><th style="width: 30%;">Reference Number</th><th style="width: 40%;">Description</th><th style="width: 30%;">Product Basic UDI-DI Number:</th></tr></thead><tbody><tr><td>3760014</td><td>HANDYBELT, S</td><td rowspan="4" style="text-align: center; vertical-align: middle;">0887761GMN000039UF</td></tr><tr><td>3760015</td><td>HANDYBELT, M</td></tr><tr><td>3760016</td><td>HANDYBELT, L</td></tr><tr><td>3760017</td><td>HANDYBELT, XL</td></tr></tbody></table>	Reference Number	Description	Product Basic UDI-DI Number:	3760014	HANDYBELT, S	0887761GMN000039UF	3760015	HANDYBELT, M	3760016	HANDYBELT, L	3760017	HANDYBELT, XL	
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Intended Purpose/Use: The belt is applied on the patient, and the caregiver then uses the belt as an aid in the transfer. 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: <ul style="list-style-type: none">• For devices with a MDR EU Certificate issued by a Notified Body:<ul style="list-style-type: none">○ 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 (<i>that are non-sterile, have no measurement function or are not reusable surgical instruments</i>) 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:	