

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).

Silhouette Sling	Document Number: NPD39194; 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: Silhouette Sling Mod.22													
<table border="1"><thead><tr><th>Reference Number</th><th>Description</th><th>Product Basic UDI-DI Number:</th></tr></thead><tbody><tr><td>3522306</td><td>SILHOUETTESLING 22 L</td><td rowspan="4">0887761GMN000038UD</td></tr><tr><td>3522603</td><td>SILHOUETTESLING 22 XS</td></tr><tr><td>3522604</td><td>SILHOUETTESLING 22 S</td></tr><tr><td>3522605</td><td>SILHOUETTESLING 22 M</td></tr></tbody></table>	Reference Number	Description	Product Basic UDI-DI Number:	3522306	SILHOUETTESLING 22 L	0887761GMN000038UD	3522603	SILHOUETTESLING 22 XS	3522604	SILHOUETTESLING 22 S	3522605	SILHOUETTESLING 22 M	
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Intended Purpose/Use: Liko Silhouette Sling is a pliable sling which adapts to the body and requires minimal space in the wheelchair. It provides for a slightly reclined sitting posture and excellent support for the entire body, which is good for patients with reduced head and torso stability. The patient can hold the arms either outside or inside the sling. The head support is adjustable. Design and material make Silhouette Sling particularly suitable for lifting to molded seats, since the sling is usually left in the wheelchair after the lifting operation is completed. This makes it very popular in care and rehabilitation situations, where sitting shells and molded seats are commonly used. Silhouette Sling can also be used in bathing and showering situations. It is intended for use in following environments: Health care, Intensive care, Emergency ward, Rehabilitation, and Habilitation.													
Device Risk Class: Class I													

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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 (<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:	