

## 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).

<b>HandyTubes &amp; HandySheets</b>	<b>Document Number:</b> NPD39200; <b>Version:</b> 3.0	
<b>Manufacturer Name and Address:</b> Liko AB and Nedre vagen 100, 975 92 Lulea, Sweden, +46 (0)920 474700		
<b>Manufacturer Single Registration Number (SRN):</b> SE-MF-000001404		
<b>Authorised Representative Name and Address:</b> Not Applicable, Registered place of business is within European union		
<b>Authorised Representative Single Registration Number (SRN):</b> 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). +++		
<b>Other relevant Directives, Regulations and Union Legislations that the device is in conformity with:</b> Not Applicable		
<b>Common Specifications Applied:</b> Not Applicable		
<b>Product/Trade Name and Product Code or REF. number:</b> HandyTubes & HandySheets		
<b>Reference Number</b>	<b>Description</b>	<b>Product Basic UDI-DI Number:</b>
1. 3710015 2. 3711015 3. 3712015 4. 3715015 5. 3715017 6. 3716015 7. 3716017 8. 3710015-10 9. 3711015-10 10. 3712015-10 11. 3715015-10 12. 3715017-10 13. 3716015-10 14. 3716017-10	1. HANDY TUBE S 2. HANDY TUBE L 3. HANDY TUBE WIDE 4. HANDY SHEET SHORT MEDIUM 5. HANDY SHEET SHORT X-LARGE 6. HANDY SHEET LONG M W/HANDLES 7. HANDY SHEET LONG XL W/HANDLES 8. HANDYTUBE SHORT 9. HANDYTUBE LONG 10. HANDYTUBE WIDE 11. HANDYSHEET SHORT MEDIUM 12. HANDYSHEET SHORT X-LARGE 13. HANDYSHEET LONG M W/HANDLES 14. HANDYSHEET LONG XL W/HANDLES	0887761GMN000040TY
<b>Intended Purpose/Use:</b> Handy Tube is a sliding sheet that is intended to move a patient higher up in the bed, turning the patient in bed, as well as moving the patient from bed to bed/gurney. It is especially used to facilitate patient transfers by reducing friction.		

## 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).

<p>HandySheet is intended to facilitate the application of the sling in a wheelchair or under the legs of the patient. HandySheet is manufactured from a low-friction material that minimizes friction between the patient and the bedding, thus reducing career workload in a number of different situations.</p> <p>It is intended for use in following environments: Health care, Intensive care, Emergency ward, Rehabilitation, and Habilitation.</p>
<b>Device Risk Class:</b> Class I
<b>MDR EU Certificate(s) No.:</b> Not Applicable
<b>Conformity Assessment Description/Annexes:</b> Annex II and III
<b>Notified Body Name and Address:</b> Not Applicable as it is class I Product
<b>Notified Body Identification Number:</b> Not Applicable as it is class I Product
<p><b>+++ This Declaration is made on the following basis:</b></p> <ul style="list-style-type: none"><li>• <b>For devices with a MDR EU Certificate issued by a Notified Body:</b><ul style="list-style-type: none"><li>○ The validity of this document shall not start earlier than the validity date of the corresponding MDR EU Certificate.</li><li>○ The DoC declares conformity to all product lots released within the validity period/dates of the corresponding MDR EU Certificate.</li></ul></li><li>• <b>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.</b></li><li>• <b>Compliance to standards and regulations as defined in the Technical Documentation and General Safety and Performance Requirements (GSPR).</b></li><li>• <b>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. +++</b></li></ul>

<b>Authorised Signatory:</b>	
<b>Name and Title:</b>	Sofie Nybom
<b>Function:</b>	QMR
<b>Place of Issue:</b>	Luleå, Sweden
<b>Date of Issue:</b>	27 - NOV - 2023
<b>Signature:</b>	