

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).

MasterVest	Document Number: NPD39190; 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: MasterVest Mod. 60 and Mod. 64		
Reference Number	Description	Product Basic UDI-DI Number:
1. 3560113 2. 3560114 3. 3560115 4. 3560116 5. 3560117 6. 3560118 7. 3564114 8. 3564115 9. 3564116 10.3564117 11.3564118	1. MASTERVEST 60 PES XS 2. MASTERVEST 60 PES S 3. MASTERVEST 60 PES M 4. MASTERVEST 60 PES L 5. MASTERVEST 60 PES XL 6. MASTERVEST 60 PES XXL 7. MASTERVEST 64 PES S 8. MASTERVEST 64 PES M 9. MASTERVEST 64 PES L 10.MASTERVEST 64 PES XL 11.MASTERVEST 64 PES XXL	0887761GMN000038UD
Intended Purpose/Use: Liko Master vest is a versatile lifting aid and an excellent help for toilet visits, standing training, gait practice mobility training and putting children in to standing tables. Front Closure Master vest can be used for patients who are able to put on and take off the vest by themselves. Front closure master vest has two adjustable safety clasps across the chest. It can be used where it is necessary to adjust the tension and regulate pressure on the chest. It is made of plastic-coated		

PARENT DOCUMENT(S): GQP-09-34
(current rev.)

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PUBLIC RELEASE

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net fabric. Friction from the material counteracts the tendency of the vest to slide upward. It can be used for bathing.

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: