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).

Multirall	**Document Number**: NPD31262; **Version** 7

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:

- The Directive 2011/65/EU (including amendment 2015/863) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Common Specifications Applied: Not Applicable

Product/Trade Name and Product Code or REF. number: Multirall 200

Reference Number	Description	Product Basic UDI-DI Number:
1. 3130001 2. 3136001 3. 3136002	1. Multirall 200 2. HANDCONTROL MR 3. HandControl MR 2-button	0887761GMN000035U7

Intended Purpose/Use:

Multirall 200 overhead lift is intended for use in all common patient lift and transfer situations, for example, between bed/wheelchair, to/ from floor, toilet visits, gait training, and for horizontal lifts with stretchers.

Intended for use in following environments: health care, intensive care, and rehabilitation.

Device Risk Class: Class I

MDR EU Certificate(s) No.: Not Applicable

Conformity Assessment Description/Annexes: Annex II and III

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).

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, Sr. Manager Quality Assurance
Function:	QMR
Place of Issue:	Lulea, Sweden
Date of Issue:	04APR2024
Signature: