

**EC installation declaration for the installation of an incomplete machine
In accordance with the Machinery Directive 2006/42/EC (Annex II Part 1 Section B)**



Manufacturer and contact person for documentation:

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Product: Linea e-lock 150, hospital bed castor with electrical detection

Year of construction: 2015

from serial number: EL2014000001-EL2024004000
35A0A4004001-35A0A9999999

We hereby confirm that the aforementioned product complies with the basic safety and health requirements listed below in accordance with Annex I of the EC Machinery Directive 2006/42/EC:

1.1.2., 1.1.3., 1.1.5., 1.1.6., 1.2., 1.2.4., 1.2.4.1., 1.2.4.3., 1.3., 1.3.4., 1.3.7., 1.4., 1.5.1., 1.5.2., 1.5.8., 1.5.10., 1.5.11., 1.7.4., 1.7.4.2., 3.5.

The special technical documents have been prepared in accordance with Annex VII Part B of the EC Machinery Directive 2006/42/EC. We undertake to submit these to the market monitoring authorities within a reasonable time upon justified request. In this case, the documents will be submitted in digital form.

Our incomplete product may only be put into operation once it has been established that the machine into which the incomplete product is to be installed complies with the provisions of the EC Machinery Directive. This also applies to an EMC test of the complete machine adapted to the area of application.

In the event of a change that has not been previously approved by us, this declaration loses its validity.

Applied directive:

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (revised version) 2006/42/EC

Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (revised version)

Applied standards:

DIN EN ISO 12100 (2011-03)

Safety of machinery – General design guidelines – Risk assessment and risk reduction (ISO 12100:2010)

DIN EN 60601-2-52

Medical Electrical Equipment - Part 2-52: Particular requirements for safety including essential performance features of medical beds (EN 60601-2-52:2010+AC2011+A1:2015)

DIN EN IEC 61000-6-2:2019-11 VDE 0839-6-2:2019-11

Electromagnetic compatibility (EMC) - Part 6-2: Basic standards- interference resistance for industrial areas (IEC 61000-6-2:2016); German version EN IEC 61000-6-2:2019

DIN EN IEC 61000-6-3:2022-06 VDE 0839-6-3:2022-06

Electromagnetic compatibility (EMC)- Part 6-3: Basic standards - disturbance emission of devices in living areas (IEC 61000-6-3:2020); German version EN IEC 61000-6-3:2021

DIN EN 12531 Hospital bed castor / wheels and castors – hospital bed castors

Wermelskirchen, 01.06.2024

TENTE-ROLLEN GmbH

Dipl.-Ing. Roland Dörner
Managing Director

German original EC installation declaration