DECLARATION OF CONFORMITY

LINAK A/S
Smedevænget 8

DK - 6430 Nordborg

hereby declares that LINAK Actuator System composed of:

Control Box COL50***0000**0****0, COL50***0000**2****0, COL50***0000**4****0, BAL50**B*******

(The '*' in the product description can either be a character or a number, thereby defining the variation of the product)

And	
Linear Actuators	20, 23, 31, 34, 40, 42, 44, KA30PL, BL1, LC1, LC3 series
And	
Controls	HB3x, HB7x, HB8x, HD8X, HB200, HB400, FS3, ACOD series
And (optional)	
Accessories	MJB2, MJB5, PJ2, CHL50

complies with the Radio Equipment Directive (RED) 2014/53/EU according to following standards:
EN 300 328 V2.2.2
EN 301 489-1 V2.2.3, EN 301 489-17 V3.2.4
EN IEC 62368-1:2020+A11
EN 62479:2010
EN 50663:2017

complies with the RoHS2 Directive 2011/65/EU according to the standard:
EN IEC 63000:2018

complies with Battery Regulation (EU) 2023/1542

Additional information:
The system does also comply with the standard:
EN 60601-1:2006+A1:2013+A2:2021+A13:2021, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2: 2015, Edition 4.0, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EMC requirements of:
EN ISO 10535:2021 Hoists for the transfer of disabled persons – Requirements and test methods

Nordborg, 2025-12-17



LINAK A/S
John Kling, B.Sc.E.E.
Regulatory Affairs Manager
Authorized to compile the relevant technical documentation

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Original Declaration