DECLARATION OF CONFORMITY

LINAK A/S
Smedevænget 8

DK - 6430 Nordborg

hereby declares that LINAK Actuator System composed of:

Battery BA21********

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

And

Control Box CA/CO series.

complies with the EMC Directive 2014/30/EU according to following standards:
EN IEC 61000-3-2:2019+A1:2021, EN 61000-3-3:2013+A1:2019+A2:2021
EN 61000-4-2:2009, EN 61000-4-4:2012, EN 61000-4-6:2014, EN IEC 61000-4-11:2020,

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

complies with Battery Regulation (EU) 2023/1542

Additional information:
The system does also comply with the standard:
EN 60601-1-2: 2015+A1, IEC Edition 4.1, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

Electromagnetic immunity performance is evaluated on system level.

Nordborg, 2024-06-14



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

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

Original Declaration