

08 July 2025

DECLARATION OF CONFORMITY

To:

- European Medical Device Regulation, MDR 2017/745
- European Radio Equipment Directive, 2014/53/EU (RED)

LiNX Bluetooth-enabled remotes

Part Number	Description
DLX-REM110-A	LiNX Remote Module - Traditional - Enhanced
DLX-REM150-A	LiNX Remote Module – Enhanced + Lights
DLX-REM210-A	LiNX Remote Module - Limited Seating
DLX-REM211-A	LiNX Remote Module - Full Seating
DLX-REM215-A	LiNX Remote Module - Lights + Limited Seating
DLX-REM216-A	LiNX Remote Module - Lights + Full Seating
DLX-REM400-B	LiNX Remote Module - Touch
DLX-REM500-A	LiNX Display Module - Touch

Dynamic Controls declares that the products specified above, as component(s) of an electrically powered wheelchair (Class I medical device), conform to all applicable requirements of the Medical Device Regulation, MDR 2017/745.

Compliance with the General Safety & Performance of MDR Annex I is demonstrated by conformance to the following standards:

ISO7176-14:2022 – Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods

EN12184:2022 - Electrically powered wheelchairs, scooters and their chargers

Note: There are no standards applying solely to such component(s). Appropriate tests, as required by the standards above, were conducted on a representative finished device fitted with this product in combination with associated control equipment.

Dynamic Controls declares that the products specified above, as component(s) of an electrically powered wheelchair (Class I medical device), conform to all applicable requirements of the Radio Equipment Directive, 2014/53/EU.

Compliance with the relevant clauses of Article 3 – Essential requirements of RED 2014/53/EU is demonstrated by use of an integrated Bluetooth module that is fully compliant with RED 2014/53/EU Essential Requirements for Health, Safety, and Radio according to the following standards:

Radio: EN 300 328 v2.1.1

Health: EN 62479:2010

Safety: EN 60950-1:2006+AMD1:2010+ A2:2013

EMC: EN 301 489-1 v2.2.0, EN 301 489-17 v3.2.0
And final product testing to meet EN 301 489-1 v2.2.3

Dynamic Controls is an ISO13485:2016 Registered Supplier. Certified by SGS on 15 September 2023,
Certificate AU02/55954.

This declaration of conformity is issued under the sole responsibility of Dynamic Controls.

For and on behalf of Dynamic Controls

Bh



Beth Gordon
Engineering Delivery Manager
Dynamic Controls
Christchurch NEW ZEALAND
Email: beth.gordon@allient.com