MANUFACTURER'S DECLARATION: MEDICAL DEVICES REGULATION 2017/745

As this component is not a complete "Medical Device" under the definition provided in the Regulation but a part with no function on its own, a Declaration of Conformity or CE mark is not appropriate until the component is incorporated. The following Declaration is issued in order to aid the installation of the component below into a finished appliance, for use by, or sale to, an end-user.

The following declares the status of these products with regard to Union Regulation 2017/745:

Product Description	Part Numbers
R-net Attendant Module	D50882, D51343

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation to the extent possible as a component to be integrated into a complete product.

APPLICABLE STANDARDS

The following standards (and those called by them) have been used in order to assess a presumption of conformity with the essential requirements of the above regulation as far as the component allows:

EN 14971:2019 + A11:2021	Medical devices — Application of risk management to medical devices
EN 62304:2006 + A1:2015	Medical device software — Software life-cycle processes
EN 10993-1:2021	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 12184:2022	Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods
ISO 7176-9:2009	Wheelchairs – Part 9: Climatic tests for electric wheelchairs
ISO 7176-14:2022	Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods
ISO 7176-21:2009	Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers

Nigel D Mills 14 June 2023

Nigel Mills, Senior Manager, Engineering

Signed at, for and on behalf of:

Penny & Giles Controls Ltd.,
15 Enterprise Way, Aviation Park West, Christchurch, Dorset, UK BH23 6HH