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	Product Name	Part Numbers
S-Drive	S45, S70, S90, S36-70	D51270, D51272, D51274, D52030
	S120, S140	D51445, D51446
	S180, S200	D51448, D51460, D51741

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
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 4 March 2024

Nigel Mills, Senior Manager, Engineering

Signed at, for and on behalf of:

Penny & Giles Controls Ltd.,
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