

**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	D51270, D51272, D51274
	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
- 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.,
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