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 Name	Product Number
Omni2 Display Module	D51709, D51752, D51755, D51784, D51793, D51819, D51836
Omni2 IO Module	D51710, D51837

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.

HARMONISED STANDARDS

The following harmonised standards (and those called by them) were used in order to attain a presumption of conformity with the essential requirements of the above directive as far as the component allows:

EN 12184:2009	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
EN 14971:2012	Medical devices — Application of risk management to medical devices
EN 62304:2006 + A1:2015	Medical device software — Software life-cycle processes
EN 12182:2012	Assistive products for persons with disability. General requirements and test methods
EN 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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Nigel Sharp, Senior Consultant Engineer

Signed at, for and on behalf of:

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