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
R-net IO Module	D50883

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 14971:2012	Medical devices — Application of risk management to medical devices
EN 62304:2006 + A1:2015	Medical device software — Software life-cycle processes
EN 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

The following are not harmonised, however called by relevant harmonised standards:

ISO 7176-9:2009	Wheelchairs – Part 9: Climatic tests for electric wheelchairs
ISO 7176-14:2008	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

18 March 2021

Nigel Sharp, Senior Consultant Engineer

Signed at, for and on behalf of:

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