MANUFACTURER'S DECLARATION: MEDICAL DEVICES REGULATION 2017/745

As this component is not a complete "Medical Device" under the definition provided in the Directive 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 Directive 2017/745:

Product Description/ Code	Product/ Part Number
R-net Bluetooth Module for iDevices	D51580

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

Nigel D Mills 23 July 2021

Nigel Mills, Senior Manager, Engineering

Signed at, for and on behalf of:

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