

**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 Name	Product Number
R-NET BLUETOOTH MODULE 2	D51523
R-NET BLUETOOTH MODULE FOR IDEVICES	D51580
R-NET BLUETOOTH MOUSE	D51111

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 Sharp, Senior Consultant Engineer

18 March 2021

Signed at, for and on behalf of:

Penny & Giles Controls Ltd.,
15 Enterprise Way,
Aviation Park West,
Christchurch,
Dorset, UK
BH23 6HH



ESR no.

*calls ISO 7176-14 and ISO 7176-21 in their entirety



Internal use only (remove from above cert. when providing to customers):

Confirm the following are present:

	Doc name	Standard date	Hyperlink
<input type="checkbox"/>	EN 12184 Test report	1999	SQ014099 (R-net PM-EL LED JSM Test Report EN 121841999)
<input checked="" type="checkbox"/>	EN 12182 Compliance		Biocompatibility Risk Assessment
<input type="checkbox"/>	EN 10993 Compliance		
<input checked="" type="checkbox"/>	EN 62304 Compliance	2006 + A1:2015	EN62304 Gap Analysis - PM090 D51109
<input checked="" type="checkbox"/>	EN 14971 Compliance	2012	See EN 62304
<input type="checkbox"/>	ISO 7176 - 9 Test report	Temperature testing performed doesn't align with standard	SQ014086 Rnet EL+LED Joystick Environmental test results
<input checked="" type="checkbox"/>	ISO 7176 - 14 Test report	2008	B12 08 47365 023, 713010286
<input type="checkbox"/>	ISO 7176 - 21 Test report	Prob. ok but not explicit alignment with standard	0565

