

**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/ Code	Product/ Part Number
R-net Chipset (and Development Kit)	D51600, D51601

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 regulation as far as the component allows:

EN 14971:2012      Medical devices — Application of risk management to medical devices  
EN 62304:2006 +    Medical device software — Software life-cycle processes  
A1:2015

*Nigel D Mills*      10 September 2021

Nigel Mills, Senior Manager, Engineering

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	N/A	N/A
<input type="checkbox"/>	EN 12182 Compliance	N/A	N/A
<input type="checkbox"/>	EN 10993 Compliance	N/A	N/A
<input checked="" type="checkbox"/>	EN 62304 Compliance	2006 + A1:2015	<a href="#">EN62304 Gap Analysis - Chipset</a>
<input checked="" type="checkbox"/>	EN 14971 Compliance	2012	See EN 62304
<input type="checkbox"/>	ISO 7176 - 9 Test report	N/A	N/A
<input type="checkbox"/>	ISO 7176 - 14 Test report	N/A	N/A
<input type="checkbox"/>	ISO 7176 - 21 Test report	N/A	N/A