

**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(s)
VR2 Dual Attendant Module	D50872

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