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:

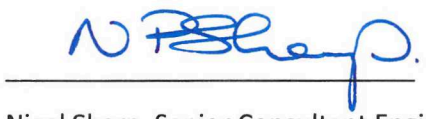
Product Name	Product Number(s)
CJSM 2	D51577, D51579, D51595, D51622, D51640, D51642, D51646, D51651, D51652, D51692, D51698, D51727, D51731

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 12184:2014	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
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 12182:2012	Assistive products for persons with disability. General requirements and test methods
EN 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process



18 March 2021

Nigel Sharp, Senior Consultant Engineer

Signed at, for and on behalf of:

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