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
R-net SPM220	D51254
R-net STLM	D51255

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 12184:2009	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:

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