

**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 Intelligent Seating Module-2 (ISM-2)	D50917, D50608, D51290, D50604
R-net Intelligent Seating Module-4 (ISM-4)	D50918, D50607, D51177, D50603
R-net Intelligent Seating Module-6 (ISM-6)	D50919, D50606, D50927, D50602, D51716, D51459, D51670, D51602, D51355, D50605

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

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Signed at, for and on behalf of:

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