

declaration of conformity

We, the manufacturer, declare in sole responsibility that the products mentioned below are in conformity with the respective regulations of the following directives.

Category	medical Body Composition Analyzer
Product:	515
EC type approval	D11-09-022
Accuracy class	III
Classification medical devices	Class IIa

Directives:

2009/23/EC Directive on non-automatic weighing instruments

93/42/EEC Directive concerning medical devices

Applied harmonised standards, national standards or other normative documents:

EN 45501 Metrological aspects of non-automatic weighing instruments

EN 60601-1 Medical electrical equipment - General requirements for basic safety and essential performance

EN 60601-1-2 Medical electrical equipment - Electromagnetic compatibility

EN 62304 Medical device software - Software life-cycle processes

EN 300 328 Electromagnetic compatibility and Radio spectrum Matters (ERM) - 2,4GHz

EN 301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM) - Common technical requirements

EN 301 489-17 Electromagnetic compatibility and Radio spectrum Matters (ERM) - Specific conditions for Broadband Data Transmission Systems

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