

EC CONFORMITY DECLARATION

Date of issue: 10. 1. 2013

Conformity declaration issued by:

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As the producer of the product - name (brand):	Multicare
Variants of the product:	1MC; with scales (Variants are specified in the technical documentation of the product).
Description and function designation:	Electrically operated hospital bed intended for use in the intensive care.
Classification of the product as the medical device:	Class Im nonsterile, with measuring function

A) Declaration

I declare that the said product is safe under the conditions of common use in compliance with the instructions and that measures have been taken to ensure the conformity of all the products brought to market with basic requirements of directives related thereto, stated in paragraph B.

B) Fulfilled technical requirements

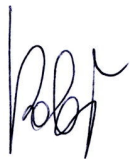
This product's characteristics comply with the technical parameters related to it and stated in directive 93/42/EEC as amended, which stipulates the technical parameters for healthcare products and in directive 90/384/EEC as amended, which stipulates the technical parameters for non automatic weighing instruments.

C) Means of assessing conformity

Conformity was assessed by the procedure stated in the directive MDD 93/42/EEC as amended, Annex VII in conjunction with Annex V.

D) Used standards

The said product fulfils the requirements of these harmonized technical standards: EN 60601-1:2006, EN 60601-1-2:2007, EN 60601-1-4:1996, EN 60601-2-52:2010, EN 980:2008, EN 1041:2008 and non harmonized technical standards: EN ISO 14971:2009, which were used for assessing of conformity.



Tomáš Kolář
managing director

