



EC Declaration of Conformity



We,

Burmeier GmbH & Co. KG
Pivitsheider Strasse 270
D – 32791 Lage / Lippe

hereby declare under sole responsibility as the manufacturer that the product model named below:

Nursing beds series

Model: Dali

in the version submitted complies with the regulations of the EC Directive 93/42/EEC Annex VII for Medical Devices, last amended by Directive 2007/47/EC dated 5 September 2007.

It is categorized as a Class I active medical device.

The relevant technical documentation is kept by the manufacturer's safety representative.

To evaluate the conformity to the Directives, all applicable parts of the following standards were referred to:

Harmonised standards:

EN 1041:2008+A1:2013

EN ISO 14971: 2012

EN ISO 15223-1:2016

EN 60601-1: 2006+Cor.:2010
+A1:2013

EN 60601-1-2: 2015

EN 60601-1-6: 2010+ A1:2015
EN 62366: 2010 +A1:2015

EN 60601-1-11: 2016

EN 60601-2-52:2010 + AC:2011 +
A1:2015

International standards:

IEC 60601-1:2005 + Cor. :2006 +
Cor. :2007 + A1:2012

IEC 60601-1-2:2014

IEC 60601-2-52: 2009-12
+AMD 1: 2015-03

Information supplied by the manufacturer of medical devices

Risk analysis for medical devices

Symbols to be used with medical device labels, labelling and information to be supplied

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

Medical electrical equipment:

Electromagnetic disturbances - Requirements and tests

Medical electrical equipment: Usability

Medical electrical equipment. Requirements for medical electrical equipment ... used in the home healthcare environment:

Medical electrical equipment:

Particular requirements for the basic safety and essential performance of medical beds

Medical electrical equipment:

General requirements for basic safety and essential performance

Medical electrical equipment:

Electromagnetic disturbances - Requirements and tests

Medical electrical equipment:

Particular requirements for the basic safety and essential performance of medical beds

Herford, 2018-06-11

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