

EC Declaration of Conformity

We,

Joh. Stieglmeyer GmbH & Co. KG
Ackerstraße 42
D-32051 Herford

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

Hospital cot
Junior

complies with the regulations of the EC Directive 93/42/EEC for Medical Products, last amended by Directive 2007/47/EC dated 5th September 2007.

It is categorised as a Class 1 inactive medical product.

The relevant technical documentation is kept by the manufacturer's safety representative. All relevant parts of the following standards were used to assess conformity to the directives:

Applied harmonised standards:

EN 716-1:2008+A1:2013	Furniture and travel cots: Safety requirements
EN 716-2:2008+A1:2013	Furniture and travel cots: Test methods
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management
EN ISO 14971:2012	Risk management for medical devices

Herford, 2014-11-20



Georgios Kampisiulis Kemmler
(Management)



Ralf Wiedemann
(Management)



EC Declaration of Conformity



We,

Stieglmeyer GmbH & CO. KG
Ackerstrasse 42,
32051 Herford, Germany

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

Hospital Bed Series: Deka

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 categorised 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 14971: 2013-04

Risk analysis for medical devices

EN 60601-1: 2007-07

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

EN 60601-1-2: 2007-12

Electromagnetic compatibility

DIN EN 60601-1-6: 2010-10

Medical electrical equipment: Usability

DIN EN 60601-2-52: 2016-04

Medical electrical equipment:
Particular requirements for the basic safety and essential performance of medical beds

International standards:

IEC 60601-2-52: 2009-12

Medical electrical equipment:

+AMD 1: 2015-03

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

IEC 62366:2007

Medical equipment: Usability

Herford, 2016-12-20

Hans-Peter Löw
(Management)

Ralf Wiedemann
(Management)

EC Declaration of Conformity

We,

Joh. Stieglmeyer GmbH & CO. Kommanditgesellschaft

Ackerstr. 42

D - 32051 Herford,

hereby declare that the product model named below:

Baby Trolley Idaro

with its mechanical adjustment devices complies with the regulations of the EC Directive 93/42/EEC for Medical Products.

This product is classified as a class I medical product (in accordance with MPG § 13, Medical Products Act).

Applied harmonised standards:

EN 14971:2007-07	Risk Management for Medical Products
DIN EN 1130:1996-07; T.1+2	Cribs and cradles for domestic use
DIN 32623:2002-07	Hospital cots made of metal and plastic

Herford, 04.01.2008



Holz
(Management)



Wiedemann
(Management)

CE declaration of conformity

We,

Joh. Stieglmeyer GmbH & CO. KG
Ackerstraße 42
D - 32051 Herford,

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

Hospital Bed **Vida**

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

It is categorised as a Class 1 active medical product.

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:

Applied harmonised standards:

DIN EN ISO 14971: 2013	Risk Analysis for Medical Products
DIN EN 60601-1: 2006	Safety for medical electrical equipment
DIN EN 60601-1-2: 2007	Electromagnetic Compatibility
DIN EN 60601-1-6: 2010	Medical electrical equipment: Suitability for intended use
DIN EN 60601-2-52: 2010	Particular requirements for the safety and essential performance of medical beds

National standards/ specifications:

Additional safety requirements for care beds of the supreme German state authority dated 22 May 2001

International standards:

IEC 60601-2-52: 2009	Medical electrical equipment: Particular requirements for the basic safety and essential performance of medical beds
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Herford, 2014-08-25


Georgios Kampisiulis Kemmler
(Management)


Ralf Wiedemann
(Management)