

EC Declaration of Conformity



We.

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

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

Hospital cot Junior

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 716-1:2008+A1:2013

Furniture and travel cots: Safety requirements

EN 716-2:2008+A1:2013

Furniture and travel cots: Test methods

EN ISO14971: 2012

Risk management for medical devices

EN ISO 10993-1:2009+AC:2010

Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management

Herford, 2019-09-12

eorgios Kampisiulis Kemmler

(Management)

Hans-Peter Löw

(Management)