

EU Declaration of Conformity

Manufacturer: Jiangsu Keling Medical Appliance Co., Ltd.
Shanian Industrial Area, Gaoyou, Jiangsu 225646, China
18, Xiaoguanqiao Road, Jiangyang Industrial Park, Yangzhou,
Jiangsu 225008, China (Factory site)

SRN: CN-MF-000003678

European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

Product Name: Hospital Bed

GMDN Code: 34870

EMDN Code: V0801

UDI-DI: 69522998HBGW

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex - II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

Jiangsu Keling Medical Appliance Co., Ltd. is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:

EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, EN 13795-1:2002, EN 13795-2:2004, EN 13795-3:2006, ISO 9073-10:2003, EN ISO 22612:2005, ISO 22610:2018.

MDCG 2019-15.

Signature:

Name:

Liu Chunhai

Position:

General Manager

Place/date

Jiangsu Province, 2021-08-10



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European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

Product Name: Operation Table

GMDN Code: 58034

EMDN Code: L9099

UDI-DI: 69522998OTJP

Classification (MDR, Annex VIII): Class I, Rule 1.

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SRN: CN-MF-000003678

European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

Product Name: Electrically Powered Wheelchair

GMDN Code: 47965

EMDN Code: Y122127

UDI-DI: 69522998EPW82

Classification (MDR, Annex VIII): Class I, Rule 1.

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SRN: CN-MF-000003678

European Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany

SRN: DE-AR-000005110

Product Name: Shadowless Operation Lamp

GMDN Code: 12282

EMDN Code: Z120107

UDI-DI: 69522998SOL9F

Classification (MDR, Annex VIII): Class I, Rule 1.

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European
Representative: Luxus Lebenswelt GmbH
Kochstr.1, 47877, Willich, Germany
SRN: DE-AR-000005110

Product Name: Wheelchair
GMDN Code: 58086
EMDN Code: Y122103
UDI-DI: 69522998WCJD

Classification (MDR, Annex VIII): Class I, Rule 1.

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