ZHANGJIAGANG MEDI MEDICAL EQUIPMENT CO.,LTD

Add: No 614 of Guotai New World Square, No.19 of east Renmin east road,

Yangshe town, Zhangjiagang City, Jiangsu Province, China

Email: info@medik-medical.com
Web: www.medik-medical.com
TEL:+86-512-58688450



Declaration of Conformity

Manufacturer: Zhangjiagang Medi Medical Equipment Co.,Ltd.

No 614 of Guotai New World Square, No.19 of east Renmin east road, Yangshe town,

Zhangjiagang City, Jiangsu Province, China

Product: Blood Donor Chair (YA-DS-M05)

Classification (MDD, Annex I,II, III & IV) Class I

Conformity assessment Route: Annex VIII

CE Notify Body: NQA

Houghton Hall Park, Warwick House, Porz Avenue, Houghton Regis, Dunstable

LU5 5ZX, United Kingdom

CE Cert No.: 03259

We, the manufacturer. herewith declare the following

Manual Hospital Bed

UMDNS-Code:10-789

Meet the provisions of Directive 93/42/EEC (amended by 2007/47/EC) which apply to them. The medical device has been assigned to (Class I) according to Annex I,II, III & IV of the Regulation (EU) 2017/745. We are exclusively responsible for Declaration of Conformity.

DIRECTIVES

General Applicable Directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993

Concerning medical devices (MDD 93/42/ECC). Amended by DIRECTIVE 2007/47/EC

Standards: EN ISO 14971:2012, EN ISO 10993-2009, EN 14126:2003, EN ISO 15223-1:2016,

EN ISO 10993-1:2018, EN ISO 10993-10:2013, EN ISO 13485: 2016

All products meet the intended use. A supporting documentation are related under the premise

manufacturer

Date

Legally Binding Signature, Function

14-DEC-2023