



Declaration of Conformity
Regarding Medical Device Regulation(EU) 2017/745

Manufacturer

Name: HEBEI JIEDE MEDICAL EQUIPMENT CO..LTD

Address:Building 5,Jizhou District Amusement Equipment Entrepreneurship Incubation Park, South side of Planning 4th Road, East side of Latt Road 3,High-Tech Development Zone,Jizhou District,Hengshui City, Hebei Province, China

SRN:CN-MF-000013052

European Authorised Representative Name: RIOMAVIX SOCIEDAD LIMITADA

Address: Calle de Almansa 55,1D,Madrid 28039 Spain

SRN:ES-AR-000001202

Product Name:Manual Medical bed,Nursing bed,Medical trolley,Bedside cabinet,Medical chair,Bed sheet, Hospital bed accessories

Model:JD-C02,JD-C04,JD-C06,JD-C07,JD-C08,JD-C09,JD-C10,JD-C11,JD-C12, JD-C13,JD-C14,JD-C15,JD-C16,JD-C17,JD-C18,JD-C19,JD-C20,JD-C21,JD-C22,JD-C23,JD-C24,JD-H03,JD-H04, JD-H05,JD-H06,JD-H07JD-MA01,JD-MA02, JD-MA03,JD-MA04,JD-MA05,JD-MA06,JD-MA07,JD-MA08,JD-MB01,JD-MB02,JD-MB03,JD-MB04,JD-MB05,JD-MB06, JD-MB07,JD-MB08,JD-MB09,JD D01-05,JD-L01-08,JD-ZA01-09,JD-ZB01-09,JD-ZC01-08,JD-ZF01-08,JD-SA01-20,JD-SB01-06,JD-SC01,JD-SD01-08,JD-FA01-15,JD-FB01-12,JD-FC01-12,JD-FD01-15,JD-FE01-12,JD-BT01-100

Basic-UDI-DI:697484796bed01AG(medical bed)

Basic-UDI-DI:697484796table01ML(beside cabinet)

Classification acc. to MDR Ax. VIII:Class I, according to MDR Annex VIII

Conformity Assessment Procedure:Annex II+III

Purpose of use of products:The beds are designed to provide a comfortable and safe bed for patients or people with limited mobility who require care in a home or nursing home environment.

We, the manufacturer, here with declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN ISO 10993-1: 2018
EN ISO 10993-5: 2009
IEC60601-1:1988
IEC60601-1-2:2001+A1:2004

EN ISO 10993-10: 2013
EN 1041: 2008+A1:2013
EN 62366-1:2015
IEC 60601-2-38:1996+A1:1999

Date of review:28.06.2023

Expiration date:28.06.2028

Signature:AmyHu



Position: General Manager

Place: Hengshui city, Hebei province,China

河北杰德医疗设备有限责任公司
HEBEI JIEDE MEDICAL EQUIPMENT CO.,LTD.