DOCUMENTATION REVIEW

S/N: 007118

No.: ICR Polska/DR/HS231221

Applicant:	HEBEI JIEDE MEDICAL EQUIPMENT CO., LTD.
address:	No.5l8 CHUNFENG STREET JIZHOU ZONE, HENGSHUI CITY, HEBEI PROVTNCE. China
Manufacturer:	HEBEI JIEDE MEDICAL EQUIPMENT CO., LTD. No.5l8 CHUNFENG STREET JIZHOU ZONE, HENGSHUI CITY, HEBEI PROVTNCE. China
Review goal:	Verification of the presence of Technical Documentation compatible with the Medical Devices Regulation (EU) 2017/745 Annexes II & III
Product:	Medical Bed
Model(s):	JD-C, JD-H, JD-MA, JD-MB, JD-SB, JD-SD, JD-FA, JD-FB, JD-FC, JD-FD, JD-L, JD-ZA, JD-ZB, JD-ZD, JD-ZE.
Product trademark:	KAIRUIJIEDE
Declared classification:	Class I (Not Sterile according to the Manufacturer's declaration – does not require the participation of a NB)
Technical Documentation:	MBTCF1208-MDR prepared by HEBEI JIEDE MEDICAL EQUIPMENT CO., LTD.
Date of review:	11.12.2023
Expiration date	10.12.2028

Review output:

- This document was issued voluntarily and at the request of the applicant.
- The above-mentioned Technical Documentation provided to us by the applicant is compatibile in terms of the general requirements for the documentation of this type of product, but its scope of review is not equivalent to Notified Body assessment and such shall be carried independently.
- The manufacturer is responsible for the CE marking process and is not exempt from carrying out all necessary activities related to the legal compliance.

International Certification ICR Registrar Ltd.

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