EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	TIANJIN GRAND PAPER INDUSTRY CO.,LTD
Address:	HONGGUANG FARM, BEICHEN DISTRICT, TIANJIN 300401, CHINA
Trademark:	/
SRN:	CN-MF-000039618
European Representative:	RIOMAVIX SOCIEDAD LIMITADA
Address:	Calle de Almansa 55, 1D, Madrid 28039 Spain
SRN:	ES-AR-000001202
Trade name:	/
Product Name:	Medical Record Paper
Product Model:	ECG, EEG, CTG, HTA, USG
EMDN Code:	Z1302
Basic UDI-DI:	69477723001Y7
Classification acc. to MDR Ax. VIII:	Class I, rule 1 of MDR Annex VIII
Applied Standard & Common Specification:	***Medical Devices Regulation 2017/745; EN ISO 13485:2016; EN ISO 14971:2019; ISO TR 24971:2020; ISO 15223-1:2021; ISO 20417: 2021; IEC 62366-1:2015+AMD1:2020; Guidance MEDDEV 2.12-1 rev. 8; MEDDEV 2.12/2 rev2; MEDDEV 2.7/1 rev.4.***
Conformity assessment procedure:	Annex IX, MDR (2017/745)
CE certificate No.:	R20240104-1
Name and ID of the Notified Body:	/

We, the manufacturer, herewith 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.

Duties : Chief Executive

Name : Li Long

Manufacturer: TIANJIN GRAND PAPER INDUSTRY CO.,LTD

Date: 31. 12. 2023

Digitally signed by Morozov Maria
Date: 2024.07.19 16:32:30 EEST
Reason: MoldSign Signature
Location: Moldova