EC Declaration of Conformity

Manufacturer:	Name: Chongqing IRC Medical Equipment Co., Ltd. Add: 402, Unit 3, Term 1, Standard Workshop, No. 98, XiYuan 2 Road, Shapingba District, 401332, Chongqing, P.R. China. SRN:CN-MF-000022476
European Representative:	Name: Riomavix S.L. Add: Calle de Almansa 55,1D,Madrid 28039 Spain SRN:ES-AR-000001202
Product Name	PERIMETER
	Model: IVS-201A,IVS-201B,IFA-900,IFA-950,IFA-960
The Basic UDI-DI for products are as follows	(01)06974525460011(21)SYJXXXXXX(11)XXXX

Classification (MDR, Rule 10): Class Ⅰ
Conformity Assessment Route: according to Annex Ⅷ of the Directive (EU)2017/745 MDR

We herewith declare in sole responsibility that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

(EU)2017/745 MDR

Medical Device Directive: COUNCIL DIRECTIVE EU 2017/745 MDR

Standards applied:

IEC 60601-1-2:2007	IEC60601-1:2005+A1:2012
ISO 10993-5:2009	ISO 10993-10-:2010

list of (harmonized) standards for which documented evidence of compliance can be provided.

Start of CE Marking: 17th May, 2022
Place of Issue: Chongqing, China
Date of Issue: 17th May, 2022

Digitally signed by Jighili Tatiana
Date: 2023.08.28 13:03:32 EEST
Reason: MoldSign Signature
Location: Moldova

Signature:

Mr. Quandi Tang

Position: General Manager