DECLARATION OF CONFORMITY

Manufacturer	RENCARE CO., LTD.
	5/F, Bldg 1, Yali Industrial Park, No.13 Tianbao Rd, Yingrenshi Community, Shiyan Street, Bao'an Shenzhen Chine
European Representative	Well Kang Ltd
	Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland;
Product Name	Holter System
Product Model	i12 plus/i12 /i3 plus /i3/Mi-Rhythm
Classification	Class IIa , Rule 10 According To Annex IX of the MDD
Procedure for Certification	Annex II excluding (4)

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THET PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES. ALL SUPPORTING DOCUMENTION IS RETAINED AT THE PREMISES OF THE MANUFACTUER.WE ARE RESPOSIBLE FOR THIS DOC.

EN 60601-1:2005/A1:2012, EN 60601-1-2:2014, EN 60601-1-6:2010/A1:2015, EN 60601-2-25-2011, EN 62304:2006+A1:2015, EN ISO 14971:2012, EN ISO 15223-1:2016. EN 1041:2008, EN/ISO 10993-1:2009/AC: 2010, EN ISO 10993-5:2009, EN ISO10993-10:2010.

Notified Body	TÜV SÜD PRODUCT SERVICE GMBH RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY
Identification Number	CE 0123
(EC) Certificate(s)	G10908130010 Rev.01
Place	Shen zhen,China
Date of issue	06.01.2021
Signature	Name: Donghong Li
Declaration Validity Date:	26.05.2024

Position: Management Representative

İşbu çevirinin aslına uygun olduğunu ve tarafsız olarak tercüme edildiğini beyan ederim.
Yeminli Mütercim Tercüman
AYLİN FATMA ŞAHİN

GÜRSOY TERCÜME
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