

## DECLARATION OF CONFORMITY

**MANUFACTURER:** TAIJIA MEDICAL ELECTRONICS (SHENZHEN) CO.,LTD.  
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PEOPLE'S REPUBLIC OF CHINA

**SRN:CN-MF-000023306**

**EUROPEAN REPRESENTATIVE:** Umedwings Netherlands B.V.  
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Tel.: +31(0) 642758955

**SRN: NL-AR-000000444**

**PRODUCT&MODEL:** ECG/ EKG CABLE (GMDN-CODE : 37200 )  
Models reference to ECG/ EKG CABLE Model List  
**BASIC UDI-DI:** 697459077ECGV4

**CONFORMITY ASSESSMENT ROUTE:** Class I, According to Rule 13, Annex VIII  
Regulation (EU) MDR 2017/745

**WE HEREWITH DECLARE THAT THE DEVICE IS COVERED BY THE PRESENT DECLARATION IS IN CONFORMITY WITH REGULATION (EU) MDR 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES AND THE EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.**

**STANDARDS APPLIED:** SEE THE LIST OF STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED

ISO10993.5-2009、ISO10993.10-2021、ISO10993.23-2021、  
EN ISO 14971:2019、ISO 15223-1:2021

**NOTIFIED BODY:** Not applicable

**PLACE, DATE OF ISSUE:** Shenzhen, 2022-11-12

**SIGNATURE:**

**Name:** Jack Ma 2022.11.12  
**Position:** Management representative



**Attachment :model list**

EZC00201520A EZC00111320A

