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中国国际贸易促进委员会



China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书

CERTIFICATE



223201A0/004182

号码 No.

兹证明：在所附文件上的广东粤华医疗器械厂有限公司的印章属实。

THIS IS TO CERTIFY THAT: the seal of GUANGDONG YUEHUA MEDICAL INSTRUMENT FACTORY CO., LTD. on the annexed DOCUMENT is genuine.



China Council for the Promotion of International Trade

授权签字:

Authorized Signature:

Zou Ruirui

日期: 2022年06月01日

(Date: Jun. 01, 2022)



Yukarıdaki imza ve mühürün **Jiangsu** Eyaleti Halk Hükümeti Dış İlişkiler Bürosu'na ait olduğu tasdik olunur.

Genel No : 31647010

Özel No : 2821

Tarih : 15.06.2022

T.C. ŞANHAY BAŞKONSOLOSELUĞU


İlker PAK
Deputy Consul General



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EC Declaration of Conformity



Regarding Medical Device Regulation (EU)2017/745

Manufacturer:

Manufacturer: Guangdong Yuehua Medical Instrument Factory Co., Ltd.
Add: Rongsheng Science and Technology Zone, Daxue Road, Shantou, Guangdong, China.
Tel: +86 0754-82525836

European Authorized Representative:

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands.

SRN: CN-MF-000004539

Product Name: Alternation Pressure Mattresses

MODEL	UDI-DI
QDC-303	694474950030LF
QDC-300B(DM-45/DM-46)	694474950047LY
QDC-602(DM-LIBRA/DM-50)	694474950057M3



Classification: Class I

Rule: According to Rule 13, Annex VIII, Chapter III of Medical Device Regulation (EU)2017/745

We, the manufacturer herewith declare in our own responsibility that the above mentioned Products meet the transposition into national law the provisions of the following EU regulation and standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Conformity assessment procedure: Annex II+III

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 14971: 2012, EN 1041:2008+A1 2013, EN ISO 15223-1: 2016, ISO 10993:2018, EN ISO 10993-5:2009, EN ISO 10993:2013, EN 60601-1, EN 60601-1-2, IEC 60417:2012, IEC 60601-1-6:2010+AMD1:2013 CSV, IEC 60601-1-11:2015 RLV, IEC TR 62366-2:2016



Signature: *[Handwritten Signature]*

Position: G.M.

Date: 2022.4.6