00987776

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.

Digitally signed by Potînga Stela
Date: 2025.06.16 13:29:14 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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)

证明网址 Website for verifying the certificate: http://www.rzccpit.com/validate.html


认字第22013334号

兹证明前面文书上中国国际贸易促进委员会商事证明专用章（27）和授权签字人（**邹锐锐**）的签字属实。

中华人民共和国外交部（320）

二〇二二年六月二日 南京

02305053

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 BAŞKONSOLOSLUĞU

İlker PAK
Deputy Consul General

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:

Position: G.M.

Date: 2022.4.6