



## 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.

UDI: 6944749500343

SRN: 63641

**Product:**

Name: Alternation Pressure Mattresses

Model: QDC-300, QDC-301, QDC-303, QDC-500, QDC-501, QDC-300B, QDC-301B, QDC-500B, QDC-501B, QDC-320, QDC-600, QDC-601, QDC-602, QDC-702, QDC-800, QDC-5010, QDC-5050, QDC-5080, QDC-8010, QDC-8050, QDC-8080, QDC-303B, QDC-303C, QDC-301W, QDC-5010E, QDC-5020, QDC-5060, QDC-5090, QDC-8020, QDC-8060, QDC-8090, QDC-9010, QDC-9020, QDC-9050, QDC-9060, QDC-9080, QDC-9090.

Talexco Model: A606/B605, A607/B605, A700/B700, A2060/B2060, A3060/B3060

**Classification:** Class I

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

**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:



Date: 2020.05.18

Position: G.M.