



# DECLARATION OF CONFORMITY

## ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer

### EU Representative

**SUNGO Europe B.V.**  
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SRN: NL-AR-000000247

### Conformity Assessment

**Conformity Assessment Procedure**  
Annex II+III of Regulation (EU) 2017/745

#### Applicable Standards

EN ISO 14971: 2012,  
EN 1041:2008+A1 2013,  
EN ISO 15223-1: 2021  
ISO 10993:2018  
ISO 10993-5:2009  
ISO 10993-10:2010  
IEC 60601-1  
IEC 60601-1-2  
IEC 60417:2012  
IEC 60601-1-11:2015

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-RFVB-01.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

### Manufacturer

**Name:** Guangdong Yuehua Medical Instrument Factory Co., Ltd.

**Address:** Science and Technology Zone, Daxue Road, Shantou, Guangdong, China

### Product Information

**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

**GMDN:** 63641

**Basic UDI-DI:** /

**Classification:** Class I

### Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date: 2021.07.31

Position: GM

Place: Guangdong/China

