



# 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.**  
**Fascinatio Boulevard 522, Unit 1.7,**  
**2909VA Capelle aan den IJssel,**  
**The Netherland**  
**SRN: NL-AR-000000247**

### Conformity Assessment

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

#### Applicable Standards

EN ISO 14971: 2019,  
EN 1041:2008+A1 2013,  
EN ISO 15223-1: 2021  
ISO 10993:2018  
ISO 10993-5:2009  
ISO 10993-10:2010  
IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV  
IEC 60601-1-2:2014+AMD1:2020 CSV  
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:** Rongsheng Science and Technology Zone, Daxue Road, Shantou, Guangdong, China

**SRN:** CN-MF-000004539

### Product Information

**Name:** Alternation Pressure Mattresses

#### Model:

QDC-303, P4000IIE(B), QDC-303+P4000IIE(B),  
QDC-300B, P4000IIE(C), QDC-300B+P4000IIE(C),  
QDC-5010E+P3000N2EB, QDC-8010+P3000A2QB3,  
QDC-8080+P3000A2QB3

**GMDN: 63641**

**Basic UDI-DI:** 694474954001M4, 694474954005MC,  
694474950030LF, 694474954004MA, 694474954006ME,  
694474950047LY, 694474950082M2, 694474950053LT,  
694474950055LX

**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:

Name: HONG, LIN

Position: GM

Date: 2022.10.18



Place: Guangdong/China