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:

Date:2022.10.18

Name: HONG, LIN

Position: GM

Place: Guangdong/China