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.

Importatore:

RICANT S.r.l.

Via Capri 26/B

20006 Pregnana Milanese (MI) Italy.

UDI-DI: 694474954003M8

SRN: CN-MF-000004539

Product:

Name: Alternation Pressure Mattresses

Model: SY400

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: 2022.03.21

Position: G.M.