



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
Tel: +31(0)10 3034500; +31(0)2021 11106

Conformity Assessment

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

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-M9001-01.

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: Kunshan Topgel Industry Co.,Ltd
Address: No.165,Xincui Road,Huaqiao
Town,Kunshan City,China(215332)

Product Information

Name: COLD HOT PACK
Model: TGHC101,TGHC102,TGHC103,TGHC104,
TGHC105,TGHC106,TGHC107,TGHC108,TGHC109
EMDN: M9001
Basic UDI-DI: /
Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

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:

Billy Huang 2023.2.17

Position: GM

Place: Kunshan/China

