



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
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards

EN ISO14971:2019
EN ISO15223-1:2021
EN ISO 20417: 2021
EN ISO10993-1:2020
EN ISO10993-5:2009
EN ISO10993-10:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-M030403-02.

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: Ningbo Chinmed Technology Co., Ltd.
Address: No.20 Xingzhong Rd, Qijiashan street, Beilun Area, Ningbo, Zhejiang Province, P.R.China
SRN: CN-MF-000023983

Product Information

Name: MEDICAL TAPE
Model: Customized
EMDN: M04010299
GMDN: 16866
Basic UDI-DI: 697286436300005A
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: 

Date: 2022.12.20

Position: GM

Place: Ningbo/China

