



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative:

Caretechion GmbH
Niederrheinstraße 71 ,40474
Düsseldorf Street,Nordrhein-Westfalen
Germany.
SRN:DE-AR-000005946

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 S0101-08 .

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:
ANHUI TIANRUN MEDICAL PACKAGING
MATERIALS CO.,LTD
Address:
No.29 of Chaoyang Road,Yixiu District, Anqing city
Anhui Province, China

SRN:CN-MF-000025544

Product Information

Name :Sterilization Pouch

Model :TRSP ,TRHFR

GMDN: 13735

EMDN: S0101

Basic UDI-DI :

Sterilization Pouch :697517679 MPPF0001HK ;

Sterilization Reel: 697517679MFR0001WZ ;

Classification :Class I ,According to Rule1,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 / 10 / 10

Name: Long Hao

Position : GM

Place: Anqing ,China

