

ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD.

ADDRESS: No.2 Building, Yingdeli Industrial Park, Wuzui Section, 206 National Road, Daqiao Development Zone,
Yixiu District, Anqing City, Anhui Province, P.R.China 246003
TEL: (+86-556) 587 7076 FAX: (+86-556) 587 7079



DECLARATION OF CONFORMITY



ACCORDING TO (EU) 2017/745 MEDICAL DEVICE

REGULATION

Manufacturer:

Name: Anhui Tianrun Medical Packaging Materials Co., Ltd.

Address: No.2 Building, Yingdeli Industrial Park, Wuzui Section, 206 National Road,
Daqiao Development Zone, Yixiu District, Anqing City, Anhui Province, P.R.China 246003

EU REPRESENTATIVE:

Name: Caretechion GmbH

Address: Niederrheinstraße 71, 40474 Düsseldorf Street, Nordrhein-Westfalen ,Germany.

Product Information:

Name: Sterilization pouch/ reel, Sterilization crepe paper, Sterilization tape, Chemical indicator strip, B-D test pack

GMDN: 13735

SRN: CN-MF-000025544

Basic UDI-DI: Sterilization Pouch :697517679 MPPF0001HK ;
Sterilization Reel: 697517679MFR0001WZ ;
Sterilization crepe paper: 697517679MCP0001V4;
Sterilization tape: 697517679MST000153;
Chemical indicator strip: 697517679MSC0001X5
B-D Test Pack: 697517679BDB0001JU

Classification: Class I ,According to Rule 1 ,Annex VIII ,Regulation (EU) 2017/745

Conformity Assessment :

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971:2019

EN ISO 15223-1 : 2016

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EN ISO 1041:2008 +A 1 : 2013

ISO 10993-5 : 2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 868-5:2019

EN ISO 11607-1: 2020

EN ISO 11140-1:2015

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017 /745 and the applicable standards above .

Remark

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

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 .

For Anhui Tianrun Medical Packaging Materials Co., Ltd.

Signature:

安徽天润医用新材料有限公司
ANHUI TIANRUN MEDICAL PACKAGING MATERIALS CO., LTD

Name: Hao Long

Date: October 10, 2022

