



DECLARATION OF CONFORMITY
ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN ISO 11140-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-BJ03.
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: Anqing Baojie Packaging Co., Ltd.
ADDRESS: No.123, XingYe RD, Development District, Anqing City, Anhui, China

Product Information

Name: Sterilization indicator strip/card
Model: Class 1, Class 4, Class 5, Class 6
GMDN: 35362
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:

Yang Xiao Dong

Date: 2021.5.21

Position: GM



Place: Anhui/China