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 868-5:2019

EN ISO 11607-1:2020

EN ISO 11140-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-BJ01.

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 pouch/roll

Model: ZFD SERIES,RFD SERIES,PMJD SERIES,LTJD SERIES

GMDN: 13735

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 Xiaodong Date: 2021.5.21

Position: GM Place: Anhui/China