



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 ISO 14971:2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2026
EN ISO 10993-1: 2025
EN ISO 10993-5:2009+A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021+A1:2025
EN 868-2:2025
EN 868-4:2025
EN 868-5:2018

Remark

*The declaration of conformity is valid in connection
with the release technical document MDR-TCF-
002.*

*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.*

File No.MDR-TCF-002-08

Manufacturer

Name: Anqing Baojie Packaging Co., Ltd
Address: No.9, Jingxin Road, Daguan District,
Anqing City, Anhui Province, China
SRN: CN-MF-000008869

Product Information

Name: Sterilization Pouch/Roll
Model: ZFD SERIES, RFD SERIES, PMJD SERIES,
LTJD SERIES, GRD SERIES, TWQ SERIES
EMDN: S01010101
Basic UDI-DI: 697109239SPR01MW
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:

Name: Yang Xiao Dong

Position: General Manager

