DECLARATION OF CONFORMITY

ACCORDING TO Annex V of Directive 93/42/EEC

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522,
Unit 1.7, 2909VA Capelle aan
den IJssel, The Netherlands

Manufacturer

Name: Anji Hengfeng Sanitary Material Co.,Ltd.
Address: Ancheng, Dipu Town 313300
Anji County Zhejiang P.R China.

Notified Body:

TÜV Rheinland, 0197

Registration number: DD 60137855 0001
Effective date: 20190415
Expiration date: 20240323

Conformity Assessment

Conformity Assessment Procedure

Annex V of Directive 93/42/EEC

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
ISO 13485:2016
ISO 10993-7:2008

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-EMSRUN-24.

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.

Product Information

Name: COMPRESSED GAUZE
Model: HFEB01 (Z-fold)
GMDN: 48131
Basic UDI-DI: 697151961HFEB01EU
Classification: Class Is
SRN: CN-MF-000013051
Intended purpose:

The compressed gauze is intended to be used to stop bleeding from wounds caused by injuries in pre-hospital emergency situations.

Declaration

We herewith declare that the above-mentioned products meet the requirements of Annex V of Directive 93/42/EEC and the applicable standards above.

Signature:

Date:2021.09.30

Position:GM

Place: ANJI, CHINA