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: DD601378550001
Effective date:20190415
Expiration date:20240323

Conformity Assessment

Conformity Assessment Procedure

Annex V of Directive 93/42/EEC

Applicable Standards

ENISO14971:2019
ENISO15223-1:2021
ENISO20417:2021
ISO10993-1:2018
ENISO10993-5:2009
ENISO10993-10:2013
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 (Rolled)
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 : A N J I , C H I N A