

## SAFERLIFE PRODUCTS COMPANY LIMITED

Floor 5, C3 building, Gaosha Industrial, Zhongcun, Panyu District, Guangzhou. 511495, China. Tel: +86 20 22091959

File No: SL/MDR -05 Version: A

### EU Declaration of Conformity

Regarding Medical Device Regulation(2017/745)

Manufacturer Name: SAFERLIFE PRODUCTS COMPANY LIMITED

Address: Floor 5, C3 building, Gaosha Industrial, Zhongcun, Panyu District, Guangzhou. 511495, China.

BASIC UDI DI: 69733000408SQ

European Representative: Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse, 80, 20537, Hamburg, Germany

Foam Dressings Model: SL815, SL816, SL817

Customer Product Name: QUICK AID

Brand Name: Dermoplast, Tiritas

Classification: I non sterile

Rule: According to Rule 1, Annex VIII, EU Medical Device Regulation (2017/745).

The conformity Assessment Procedure according to Article 52(7) has been performed and the technical documentation is kept available.

This EU-Declaration of Conformity is issued under the sole responsibility of SAFERLIFE PRODUCTS COMPANY LIMITED.

We declare that the product described above meets the applicable provisions, in particular, the General Safety and Performance Requirements of the EU-legislation "Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices" and the following harmonized standards:

EN ISO 14971:2019

EN ISO 15223-1:2016

EN 1041:2008

EN ISO 10993-1:2018

EN ISO 10993-5:2019

EN ISO 10993-10:2019

Signature: 

Name: Erric Tan

Position: Operation Director

Date: March 25, 2020

