

## Declaration of Conformity

1. Manufacturer: Zhende Medical Co.,Ltd.  
Gaobu Town, 312035, Shaoxing, Zhejiang, China
2. EC Representative: Shanghai international Holding Corp.GmbH(Europe)  
Eiffestrasse 80 20537 Hamburg Germany
3. Product name First Aid Kit (include Combi-bags first aid kit)  
GMDN Code: 11723
4. Classification (MDD, Annex IX): Is, rule 4  
Conformity Assessment Route: Annex V section 3

We herein declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

### DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

5. Standard Applied:

EN 15223-1: 2016    EN 1041:2008    EN ISO 13485:2016  
EN ISO 14971:2012    DIN 13164:2014

6. Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse, 65, 80339

München, Germany

NB Identification number: 0123

7. (EC) Certificate(s): G2S 095972 0004 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2016-07-27

Place, Date of Issue: Shaoxing, Zhejiang, China, 2016-07-27 (First Aid Kit)

Signature: 

Name: Chen Ming

Date: 2021.06.08

Position: Quality Director

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