



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 Sterile Adhesive Surgical Dressing
Please refer to the Product List for detailed information.
UMDNS Code: 17428
- Classification (MDD, Annex IX): Is, rule 4
Conformity Assessment Route: Annex V

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.

Standard Applied:

EN ISO 15223-1:2016
EN ISO 13485:2016

EN 1041:2008+A1:2013
EN ISO 14971:2012

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr, 65,
80339 München, Germany

NB Identification number: 0123

(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, 2021.04.08

Signature: 

Name: Chen Ming

Position: Regulatory Director



Product List

S/N	REF No.	Product Description
1	4750	ABE Wundschnellverband
2	4752	ABE Wundschnellverband
3	4754	ABE Wundschnellverband
4	4760	ABE Wundschnellverband
5	4762	ABE Wundschnellverband
6	4764	ABE Wundschnellverband
7	4768	ABE Wundschnellverband
8	9571	ABE derm
9	9572	ABE derm
10	9573	ABE derm
11	9580	ABE derm plus
12	9581	ABE derm plus
13	9584	ABE derm plus
14	9585	ABE derm plus