



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 Absorbent Pad
UMDNS Code: 11326

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 92/42/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, 2022.01.05

Signature:  _____

Name: Chen Ming

Position: Regulatory Director



Product List

S/N	REF No.	Product Description	Specification
1	135530Z	EUROVIT STERILE	10 X 10 cm
2	135540Z	EUROVIT BLUE STERILE	10 X 10 cm
3	135532Z	EUROVIT STERILE	10 X 20 cm
4	135542Z	EUROVIT BLUE STERILE	10 X 20 cm
5	135534Z	EUROVIT STERILE	15 X 20 cm
6	135544Z	EUROVIT BLUE STERILE	15 X 20 cm
7	135535Z	EUROVIT STERILE	15 X 25 cm
8	135536Z	EUROVIT STERILE	20 X 20 cm
9	135546Z	EUROVIT BLUE STERILE	20 X 20 cm
10	135537Z	EUROVIT STERILE	20 X 25cm
11	135547Z	EUROVIT BLUE STERILE	20 X 25 cm
12	135539Z	EUROVIT STERILE	20 X 40 cm
13	135537Z	EUROVIT STERILE	20 X 25 cm
14	135547Z	EUROVIT BLUE STERILE	20 X 25 cm
15	135539Z	EUROVIT STERILE	20 X 40 cm