

Declaration of Conformity

- Manufacturer: Xuchang Zhende Surgical Dressing Co., Ltd.
 Site 1: No.1, Jinhui Road, Industry Cluster District, Yanling County 461200 Xuchang City, Henan Province, PEOPLE'S REPUBLIC OF CHINA.
 Site 2 (Legal manufacturer): Area A, Baihua Road East, South Side of Erji river, Industry Cluster District Yanling County 461200 Xuchang, Henan PEOPLE'S REPUBLIC OF CHINA
- EC Representative: Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80 20537 Hamburg Germany
- Product name: Lap Sponge
 UMDNS Code: 15085
- 4. Classification (MDD, Annex IX): Ila, rule 7

Conformity Assessment Route: Annex II excluding (4)

Statement:

We hereby declare in our own responsibility 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. We are exclusively responsible for the declaration of conformity.

5. DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

(MDD 93/42/EEC).

 Standard Applied:

 EN ISO 13485:2016
 EN ISO 14971:2019

 EN ISO 15223-1:2021
 EN 14079:2003

6. Notified Body: TÜV SÜD Product Service GmbH,

Ridlerstraβe 65·80339 München, Germany

NB Identification number: 0123

- 7. (EC) Certificate(s): G1 109397 0004 Rev.00
- 8. Start of CE Marking: 2009-03-04
- 9. Expire date of the Certificate: 2024-03-03

Place, date of issuing the certificate: Henan, 2020-11-10

Signature:

Date: 2023-01-11

Name: Chen Ming

Position: Regulatory Director



Product list			
	S/N	REF	Product description
	1	453018	Telasorb 45*45cm-4p
	2	453019	Telasorb 45*45cm-6p