

Declaration of Conformity

1. Manufacturer:

Name: Zhende Medical Co., Ltd.
Address: Gaobu Town, 312035, Shaoxing, Zhejiang, China
SRN: CN-MF-000009961

2. Authorised Representative:

Name: Shanghai international Holding Corp.GmbH(Europe)
Address: Eiffeustraße 80, 20537 Hamburg, Germany.
SRN: DE-AR-000000001

3. Product Name: Non-sterile Ostomy Appliances

Basic UDI-DI: 69593857NOA000001AJ

4. Intended use: Non-sterile Ostomy Appliances are used as a receptacle for collection of fecal material or urine. The Ostomy Appliances contact to stoma or mucous membrane.

5. EMDN Code: A1001/ A1002/ A100302/ A108001/ A108002/ A108003/A108099

6. Classification: Class I non-sterile

Based on MDR EU2017/745 Annex VIII rule 4:

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates.


7. Statement: We declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of Zhende Medical Co., Ltd.

8. Common Specification: NA

9. Standard Applied:

EN ISO 15223-1:2021 EN ISO 13485:2016 EN ISO 14971:2019

Place, Date of Issue: Shaoxing, Zhejiang. 2024.7.25

Signature: 

Name: Chen Ming

Position:Regulatory Director

Product List

S/N	REF	Product name	Description	Intended use
1	2022483	Ally Rings	diameter 48mm, thickness 3mm	Ostomy ring can be used to fill in or caulk uneven skin contours near the stoma to create a flatter surface and help prevent ostomy drainage from getting under the ostomy baseplate. They may be cut, stretched, or stacked together to help improve the fit of a pouching system.
2	2022484	Ally Rings	diameter 48mm, thickness 4.5mm	
3	2022983	Ally Rings	diameter 98mm, thickness 3mm	
4	2022482	Ally Rings	diameter 48mm, thickness 2.2mm	
5	2022100	Ally Powder	28g/bottle	Ostomy powder is used to absorb moisture from skin around the stoma, which allows for better baseplate adhesion to help protect the skin.
6	2022200	Ally Paste	80g/tube	Paste is intended to fill in cavities/ folds in the intact skin around the stoma. This provides a seal between the stoma and the ostomy base plate and protects the skin against the stoma output.
7	2022300	Ally Wafer Extenders	R: 80mm	Elastic tape is designed to stick around the edges of your baseplate, to prevent the edges of the baseplate from lifting and rolling and keeps your baseplate securely in place. It is elastic so it follows body contours and movements. It can absorb moisture, and it is also skin-friendly.