



Declaration of Conformity

1. Manufacturer: Henan Zhende Medical Products Co.,Ltd.
Baihua Road West, North Side of Jinhui Road, Industry Cluster District,
Yanling County, 461200, Henan , China
2. EC Representative: Shanghai international Holding Corp. GmbH (Europe)
Eiffestrasße 80 - 20537 Hamburg Germany
3. Product name: Non-woven products
UMDNS code: 15252
4. Classification (MDD, Annex IX): Is, Rule 4
Conformity Assessment Route: Annex V, section 3

5. Statement:

We hereby 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.

6. DIRECTIVES

General applicable directives:

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

7. Standard Applied:

EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223-1:2016 EN 1041:2008+A1:2013
EN 14079:2003

8. Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstrasse 65-80339 München, Germany

NB Identification number: 0123

9. (EC) Certificate(s): G2S001594 0002 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2017-11-10

Place of Issue: Xuchang, Henan

Signature:

Date: 2021-12-31

Name: Chen Ming

Position: Regulatory Director

Product list

S/N	REF	Product
1	7022	Nonwoven Swabs 30g/m ² 10*10cm-4P
2	221607	Nonwoven Swabs 30g/m ² 10*10cm-4P
3	7033	Nonwoven Swabs 30g/m ² 10*20cm-4P
4	221605	Nonwoven Swabs 30g/m ² 5*5cm-4P
5	7013	Nonwoven Swabs 30g/m ² 5*5cm-4P
6	221606	Nonwoven Swabs 30g/m ² 7.5*7.5cm-4P
7	7023	Nonwoven Swabs 30g/m ² 10*10cm-4P
8	7012	Nonwoven Swabs 30g/m ² 5*5cm-4P
9	7017	Nonwoven Swabs 30g/m ² 7.5*7.5cm-4P
10	7018	Nonwoven Swabs 30g/m ² 7.5*7.5cm-4P
11	7032	Nonwoven Swabs 30g/m ² 10*20cm-4P