



Declaration of Conformity

1. Manufacturer:

Name: Henan Zhende Medical Products Co., Ltd.

Address: Building C and D, No.3 Weilai Road, Industry Cluster District, Yanling County 461200,
Xuchang, Henan, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000009621

2. European Representative:

Name: CMC Medical Devices & Drugs S.L.

Address: C/Horacio Lengo,18, 29006, Málaga, Spain.

SRN: ES-AR-000000293

3. Notified Body:

✓ 3.1 NB for MDR

Name: Intertek Medical Notified Body AB

Address: Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden.

Identification number: 2862

✓ 3.2 NB for PPE

Name: SGS Fimko OY

Address: Takomotie 8, FI-00380 Helsinki, Finland

Identification number: 0598

4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability:

Product list refer to in the end of the DoC

5. EMDN Code: T01010102 SURGICAL GLOVES, LATEX, NON-POWDERED

6. Intended Use:

It is used to be worn on the hands of surgical personnel to prevent the spread of dander and bacteria to the open surgical wound, and to prevent the spread of body fluids of surgical patients to medical personnel, playing the role of bidirectional biological protection.

7. Classification:

✓ 7.1 For MDR: Class IIa



Based on MDR REGULATION (EU) 2017/745 Annex VIII rule 7

The specific sentence is: All surgically invasive devices intended for short-term use are classified as IIa

✓ 7.2 For PPE: Catagory III

Based on PPE REGULATION (EU) 2016/425 Annex I

8. Conformity Assessment Route:

EU MDR 2017/745 Annex IX Chapter I and III

PPE 2016/425 Annex V (module B) and Annex VIII (module D)

9. Statement:

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

The EU declaration of conformity shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.

✓ 9.1 For MDR

We hereby 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.

✓ 9.2 For PPE

In conformity with the provisions of regulation (EU) 2016/425 of the European parliament and of the council of 9 March 2016 on Personal protective equipment, and Conformity with the requirements of above regulation is testified by complete adherence to the following technical specifications listed in point 11.2 in this DoC

Identical to the PPE which is the subject of EU type-examination for Regulation (EU) 2016/425 (module B) issued by: Notified Body No. 0598, SGS Fimko OY, Takomotie 8, FI-00380 Helsinki, Finland.

Identical to the PPE which is subject to the procedure set out in module D of Regulation (EU) 2016/425 Personal Protective Equipment under the supervision of the notified body SGS Fimko OY, Takomotie 8,FI-00380 Helsinki, Finland, Notified Body number:0598.

10. CS: NA

11. Standard Applied:



✓ 11.1 For MDR section:

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

EN 455-1:2020 EN 455-2:2015 EN 455-3:2015 EN 455-4:2009

✓ 11.2 For PPE section:

EN ISO 21420:2020, EN ISO 374-1:2016, EN374-2:2014, EN 374-4:2013, EN ISO 374-5:2016,
EN 16523-1:2015

12. (EC) Certificate(s):

✓ For MDR section:

Number of the Certificate: 28620191190

Expire date of the Certificate: 26 June 2028

Issue date of the certificate: 25 September 2024

✓ For PPE section:

Number of the Certificate: 0598/PPE/24/2199

Expire date of the Certificate: 2029-01-25

Issue date of the certificate: 2026-03-06

Place and date [Henan, China, 2026.03.17] of issue of the declaration,
name and function [Chen Ming, Regulatory Director] of the person who signed it
as well as an indication for, and on behalf of whom [Henan Zhende Medical Products Co., Ltd.],
that person signed, signature.

Signature:

A handwritten signature in black ink, appearing to be 'Chen Ming' in a stylized cursive script.

Name: Chen Ming

Position: Regulatory Director



Product list

	Variants list	REF	color	size	Model number
1	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420280	cream	5.5	TB01
2	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420281	cream	6.0	TB01
3	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420282	cream	6.5	TB01
4	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420283	cream	7.0	TB01
5	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420284	cream	7.5	TB01
6	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420285	cream	8.0	TB01
7	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420286	cream	8.5	TB01
8	Surgical Gloves Sentinex Latex Touch, sterile Basic UDI-DI, 697240342LSG000001SU	420287	cream	9.0	TB01
9	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420290	green	5.5	TB01
10	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420291	green	6.0	TB01



	Variants list	REF	color	size	Model number
11	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420292	green	6.5	TB01
12	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420293	green	7.0	TB01
13	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420294	green	7.5	TB01
14	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420295	green	8.0	TB01
15	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420296	green	8.5	TB01
16	Surgical Gloves, Sentinex Latex Underglove, sterile Basic UDI-DI, 697240342LSG000001SU	420297	green	9.0	TB01
17	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420300	cream/ green	5.5	TB01
18	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420301	cream/ green	6.0	TB01
19	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420302	cream/ green	6.5	TB01
20	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420303	cream/ green	7.0	TB01



	Variants list	REF	color	size	Model number
21	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420304	cream/ green	7.5	TB01
22	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420305	cream/ green	8.0	TB01
23	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420306	cream/ green	8.5	TB01
24	Surgical Gloves, Sentinex Latex Double, sterile Basic UDI-DI, 697240342LSG000001SU	420307	cream/ green	9.0	TB01