GIOTECH
吉 澳 科 技

Room D-209, No.85 Luojia Cun Shilian Road,
Dalong Street Panyu District Guangzhou,
511430 China

# EU Declaration of Conformity

## GUANGZHOU GIOTECH CO., LTD

We hereby declare under our sole responsibility that the above-mentioned products comply with the requirements of the Medical Device Regulation (EU) **2017/745** of 5 April 2017 and the Personal Protective Equipment Regulation (EU) **2016 /425** of 9 March 2016. This statement is supported by the approval of the ISO 13485:2016 Quality System issued by NQA (Reg. No. 131072). For the following products,

**Product name or:**
NON-STERILE NITRILE EXAMINATION GLOVES
**UDI Basic:** 697607145GN-001B3

**Product reference(s):**

- Sensicecs PF: 28042 Size S, 28043 Size M, 28044 Size L, 28045 Size XL.
- SuperNitricecs PF: 28501 Size XS, 28502 Size S, 28503 Size M, 28504 Size L, 28505 Size XL.
- SuperNitricecs Plus PF: 28602 Size S, 28603 Size M, 28604 Size L, 28605 Size XL.
- Nitricecs Negro PF: 66002 Size S, 66003 Size M, 66004 Size L, 66005 Size XL.
- BlackNitricecs Plus PF: 66012 Size S, 66013 Size M, 66014 Size L, 66015 Size XL.
- Maxnitricecs Blue LG: 36012 Size S, 36013 Size M, 36014 Size L, 66005 Size XL.
- MaxNitricecs Negro PF: 36612 Size S, 36613 Size M, 36614 Size L, 36615 Size XL.
- MaxNitricecs Verde 610: 36002 Size S, 36003 Size M, 36004 Size L, 36005 Size XL.
- Ocean box 30 UD: 13002 Size S, 13003 Size M, 13004 Size L; 13005 Size XL.

**GMDN Code:** 56286

**Intended purpose:** Hand protection, used to prevent the transmission of a wide variety of diseases to both patients and healthcare workers.

**Risk classification:** Class I, according to Regulation 1 and 5 of Annex VIII to Regulation on Medical Devices (EU) **2017/745** of 5 April 2017

**Conformity assessment procedure:** Annex II and III

**Risk classification of PPE:** Category III according to Annex V of EU Regulation **2016/425** on Personal Protective Equipment.

**Conformity assessment procedure for Personal Protective Equipment:**

**Module B** in Annex V to the EU Regulations Standard: **2777/20730-02/E00-00**
Notified Body: **SATRA (2777)**

**Module C2** in Annex VII of the Regulation: Conformity based on internal production control and supervised product control at different random intervals.

For the evaluation of the compliance with the regulation, the following standards were applied:

| Standard | Title | Edition/date |
|---|---|---|
| EN 455-1 | Single-use medical gloves: requirements and tests for absence of holes. | 2000 |
| EN 455-2 | Single-use medical gloves: requirements and tests for physical properties. | 2015 |
| EN 455-3 | Single-use medical gloves: requirements and tests for biological evaluation. | 2015 |
| EN 455-4 | Single-use medical gloves: requirements and tests for determining the shelf life. | 2009 |
| ISO 2859-1 | Sampling procedures for attribute inspection - Part 1: sampling plans indexed by acceptable quality level (AQL) for batch-by-batch inspection. | 1993 |
| EN ISO 21420 | Protective gloves. General requirements and test methods. | 2020 |
| EN ISO 374-1 | Protective gloves against hazardous chemicals and microorganisms - Part 1: terminology and performance requirements for chemical risk. | 2016 +A1:2018 Type B |
| EN ISO 374-4 | Protective gloves against chemicals and microorganisms. Part 4: Determination of resistance to chemical degradation. | 2019 |
| EN ISO 374-5 | Protective gloves against hazardous chemicals and microorganisms. Part 5: terminology and performance requirements for microbiological risk. | 2016 |

The responsible for this declarations:
(X) **Manufacturer**:

**GUANGZHOU GIOTECH CO., LTD**.
Address: Room 209, Building 4, No.85 Luojia Village Shilian Road, Dalong Street, Panyu District, Guangzhou City, Guangdong Province, P.R. China
(T) 862084508229 ~ (F) 862084508229
**SRN:** CN-MF-000040631

(X) **Authorized legal representative in the European Union:**

**ICEMEDICS, S. L.**
Calle Eduardo Torroja, 38
28946 Fuenlabrada (Madrid)
SPAIN
**SRN:** ES-AR-000035147

This Declaration of Conformity is issued under the responsibility of:

**GUANGZHOU GIOTECH CO., LTD.**
Address: Room 209, Building 4, No.85 Luojia Village Shilian Road, Dalong Street, Panyu District, Guangzhou City, Guangdong Province, P.R. China
(T) 862084508229 ~ (F) 862084508229


**Name and surname:**
**Position:** General Manager
**Date:** March 23, 2023