GIOTECH
吉 澳 科 技

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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 VINYL EXAMINATION GLOVES
UDI Basic: 697607145GV-001DT

Product reference(s):

- SuperVinicecs Pro PF: 12111 Size XS, 12112 Size S, 12113 Size M, 12114 Size L, 12115 Size XL
- SuperVinicecs Blue PF: 12021 Size XS, 12022 Size S, 12023 Size M, 12024 Size L, 12025 Size XL
- Vinicecs PF: 12011 Size XS, 12012 Size S, 12013 Size M, 12014 Size L, 12015 Size XL

GMDN Code: 47176

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: **2777/20730-01/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**:

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This Declaration of Conformity is issued under the responsibility of:

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Name and surname:
Position: **General Manager**
Date: Jan 16, 2023