EU DECLARATION OF CONFORMITY

Doc No.: MDR/PPER/IN/GBLU-01

Identification of the Legal Manufacturer & Address:	Shandong Intco Medical Products Co., Ltd. Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China
European Authorized Representative:	Lotus NL B.V. Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands Email: peter@loutsnl.com
Basic UDI-DI:	697024575Nitrile7G
Product reference:	SNV/B/H/PE10013 - SNV/B/H/PE10017
Product & Identification:	**GLOVTEC Blue Disposable Nitrile Examination Gloves, Powder Free**
Intended purpose of the product:	The Disposable Nitrile Examination Gloves is a disposable product intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.
GMDN code and product:	**56286 Nitrile examination/treatment glove, non-powdered, non-sterile**
EMDN code:	**T010202024 GUANTI NON CHIRURGICI IN NITRILE** EXAMINATION / TREATMENT GLOVES, NITRILE
Manufacturer SRN Number: **REP SRN Number:**	CN-MF-000002100 NL-AP-000000121
Classification (MDR):	Class 1, Non-sterile, no measuring function and not surgical instrument
Classification (PPER):	Category III

- **We hereby declare that the above mentioned devices comply with the European Medical Device Regulations (EU) MDR 2017/745. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.**
- **We hereby declare that our EU Type examination Certificate Conformity the requirements of Annex V (Module B) of the regulation (EU) 2016/425 of the European Parliament and of the council. Follow the EU Type-Examination of the products has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.**

Conformity Assessment Procedure (MDR):	Article 52(7) and Annex VIII, 4.1 Rule 1, Non-invasive device, and/or 5.1 intended for transient use, Rule 5 of invasive device.
Conformity Route (MDR):	Self-Declaration
Relevant Harmonized Standards (MDR):	EN ISO13485:2016, EN 455-1: 2020, EN455-2:2015, EN455-3:2015, EN455-4:2009
Quality System Certificate:	ISO 13485:2016 Certificate No: 0086238-02 Certificate Body: Intertek Testing Services NA Ltd. Issued Date: 31 December 2021 Valid Date: 31 December 2024
Relevant Standards (PPER):	EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018 (Typ B); EN ISO 374-2:2019; EN ISO 374-4:2019; EN ISO 374-5:2016; EN 16523-1:2015+A1:2018; ISO 16604:2004
Assessment Procedure (PPER):	Module C2
EU Type Examination Certificate Number:	2777/17447-02/E00-00
Certification Body (PPER):	SATRA Technology European Limited
Notified Body (PPER):	2777

Applicable Standards (MDR):

No	Standard	Descriptions	Date Published
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement and testing for freedom from holes.	May 2020
2	EN 455-2:2015	Medical gloves for single use. Part 2: Requirement and testing for physical properties.	April 2015
3	EN 455-3:2015	Medical gloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
4	EN 455-4:2009	Medical gloves for single use. Part 4: Requirements and testing for shelf life determination.	October 2009
5	EN ISO 14971:2019	Medical device - Application of risk management to medical device.	December 2019
6	EN 62366-1:2015	Medical Devices-Part 1: Application of usability engineering to medical devices	April 2015
7	ISO 2859-1:2011	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	June 2011
8	ISO 10993-1:2018	Biological evaluation for medical device -Part 1: Evaluation and testing within a risk management process	August 2018
9	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	June 2009
10	EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitization.	August 2013
11	EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity	June 2018
12	ISO 10993-12:2012	Biological evaluation for medical devices - Sample preparation and reference materials	July 2012
13	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied: General requirements.	July 2021
14	MDR 2017/745 (Annex 1: Chapter 2)	Requirements Regarding Design and Manufacture	April 2017
15	MDR 2017/745 (Chapter 1: Article 2)	Scope and Definitions	April 2017
16	MDR 2017/745 (Annex VIII)	Classification rules	April 2017
17	MDR 2017/745 (Annex II)	Technical Documentation	April 2017
18	MDR 2017/745 (Chapter II: Article 11&12)	Guideline for Authorized Representative	April 2017
19	MDR 2017/745 (Annex XIV: Part A)	Clinical Evaluation	April 2017
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4, June 2016
21	MEDDEV 2.12-1 rev 8	Medical Device Vigilance System	January 2013
22	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
23	MDR 2017/745 (Chapter VII: Section 2: Article 87-92)	Vigilance	April 2017
24	MDR 2017/745 (Annex XIV: Part B)	Post Market Clinical Follow-up Studies	April 2017
25	MEDDEV 2.12/2	2.12/2 Post Market Clinical Follow-up Studies	Revision 2, January 2012
26	MDR 2017/745 (Chapter VII: Section 1: Article 83-86) Annex III	Post Marketing Surveillance (PMS)	April 2017
27	MEDDEV 2.12/Recl	2.12 Post - Marketing Surveillance (PMS) post market / production	Revision 11, February 2000
28	MDR 2017/745	Medical Device Regulation	April 2017
29	EN 1041:2008 + A1 2013	Information supplied by the manufacturer of medical devices	December 2019
30	ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation	January 2021

Identification of the person authorized to sign on behalf of the Legal Manufacturer:

Signed by: Rick Cheng

Print Name: Rick Cheng
Title: Quality Manager
Place: Shandong, China
Date: 01 September 2022