EU DECLARATION OF CONFORMITY

Doc No.: MDR/PPER/IN/CLA-02

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:	EC REP 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(23/33/43/53) - SNV/B/H/PE10017(27/37/47/57) XS-XXL: CL0010124-624 CL2230124-624 CL3230124-624 CL0120124-624 CL1230124-624
Product & Identification:	**CLARA 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:	**T01020204 GUANTI NON CHIRURGICI IN NITRILE** EXAMINATION / TREATMENT GLOVES, NITRILE
Manufacturer SRN Number: **REP SRN Number:**	CN-MF-000002100 NL-AR-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: 0086238-03 Certificate Body: Intertek Testing Services NA Ltd. Issued Date: 13 December 2024 Valid Date: 31 December 2027
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 D
EU Type Examination Certificate Number:	2777/17447-03/E00-00, 2777/17447-03/E45-01
Certification Body (PPER):	SATRA Technology European Limited
Notified Body (PPER):	2777

Applicable Standards (MDR):

No	Standard	Descriptions	DatePublished
1	EN 455-1:2020	Medical gloves for single use. Part 1: Requirement andtesting for freedom from holes.	May 2020
2	Efi 455-2:2015	Medical gloves for single use. Part 2:Requirement and testing for physical properties	April 2015
3	Efi 455-3:2015	Medicalgloves for single use. Part 3: Requirement and testing for biological evaluation.	April 2015
4	EN 455-4:2009	Medicalgloves for singleuse. Part 4: Requirements and testing for shelf life determination.	October 2009
5	Efi ISO 14971 2019	Medical device- Application ofrisk 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-lotinspection	June 2011
8	ISO 10993-1:2018	Biological evaluation for medical device -Part 1: Evaluation and testingwithin a risk management process	August 2018
9	ISO 10993-5:2009	Biological evaluation ofmedical devices -Part 5: Tests for in vitro cytotoxicity	June 2009
10	EN ISO 10993-10:2013	Biologicalevaluation ofmedical devices - Tests for irijaj ion 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 beused with medicaldevice labels, labeling andinformation to be supplied: General iequirenents.	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)	ScopeandDefinitions	April 2017
16	MDR 2017/745(Annex VIII)	Classification rules	April2017
17	MDR 2017/745(Annex III)	Technical Documentation	April2017
18	MDR 20177745(Chapter It: Artide 11&12)	Guideline for Authorized Representative	April2017
19	MDR 2017/745(Annex XIV: PartA)	Clinical Evaluation	April2017
20	MEDDEV 2.7/1	2.7/1 Clinical Evaluation	Revision 4,June 2016
21	MEDDEV 2.12-1 rev 8	Medical Device VigilanceSystem	January2013
22	MEDDEV 2.12/1	2.12/1 Medical Device Vigilance System	Revision 8, January 2013
23	MDR 20177745(fihapter VII: Section 2:Ajticle 87-92)	Vigilance	April2017
24	MDR 2017/745(Annex XjV: Part B)	Post Market Clinical Follow-up Studies	April 2017
25	MEDDEV 2.12/2	2.12/2 Post Maket Clinical Follow-up Studies	Revision 2, January 2012
26	MDR 2017/745 (Chapter VII: Section 1:Article83-86)AnnexIII	Post Marketing Surveillance(PMS)	April 2017
27	MEDDEV 2.12 Red /	2.12 Post - Marketing Surveillance (PMS) post market /	Revision 11,
28	MDR 2017/745	pioductiion Medical Device Regulation	February 2000 April2019
29	fiN 1041:2008 +A12013	Infomationsnpilledbythemannfactreiofmefiicaldevices	December2019
30	ISO 10993-23: 021 :2	Biological evaluation of medifiel devices- Part 23: Tests for iritation	January 2021

Identficagionof thep rson authorized to sign onb half of the Legal Manufacjurer:

Signed by:

Jile: Quality Manage
Place: Shanarng, china
Date:3rd February2025