

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:**



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:

CN-MF-000002100

REP SRN Number:

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	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:

Title: Quality Manager

Place: Shandong, China

Date: 3rd February 2025

