ICONIC MEDICARE SDN BHD

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
Iconic Medicare Sdn Bhd	*PMT 798, Lingkaran Cassia Selatan, Taman Perindustrian Batu Kawan, 14110, Bandar Cassia, Pulau Pinang.*	*MY-MF-000002919*

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Phone/email**
Emergo Europe	*Prinsessegracht 20 2514 AP The Hague The Netherlands.*	*NL-AR-000000116*	*+31.70.345.8570 EmergoEurope@ul.com*

PRODUCT IDENTIFICATION		
Product Name	**Code / Catalog Number**	**Basic UDI-DI**
Iconic Nitrile Examination Glove	*NEG*	*9551010281MCNPFEGTJ*
Intended Purpose	**Photo**	
For Medical Examination purpose, which is used by medical professionals for prevention of transmission disease by avoid contaminations to patient.	-	

	DECLARATION OF CONFORMITY: ICONIC NITRILE EXAMINATION GLOVE	DOCUMENT NO	IMC/MDQMS/10	FIELD OF APPLICATION
		REVISION NO	01	
		EFFECTIVE DATE	5TH APRIL 2022	■ GLOVE
		PAGE	2 OF 2	☐ MASK

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standard
Class:	1	1. **EN 455-1:2000** *(Medical gloves for single use – Part 1: Requirements and testing for freedom from holes).* 2. **EN 455-2:2015** *(Medical gloves for single use – Part 2: Requirements and testing for physical properties).* 3. **EN 455-3:2015** *(Medical gloves for single use - Part 3: Requirements and testing for biological evaluation).* 4. **EN 455-4:2009** *(Medical gloves for single use - Part 4: Requirements and testing for shelf life determination).* 5. **ISO 10993-5:2009** *(Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity).* 6. **ISO 10993-10:2010** *(Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization).* 7. **ISO 10993-11:2017** *(Biological evaluation of medical devices — Part 11: Tests for systemic toxicity).* 8. **ISO 10993-23:2021** *(Biological evaluation of medical devices — Part 23: Tests for irritation).* 9. **ASTM D6319-10** *(Standard Specification for Nitrile Examination Gloves for Medical Application).* 10. **ASTM D6978-05** *(Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs).* 11. **ISO 374-1** *(Protective gloves against dangerous chemicals and micro-organisms).*
Rule:	5	12. **ISO 374-2 (***(Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration).* 13. **EN 16523-1:2015+A1.2018** *(Determination of material resistance to permeation by chemicals – Part 1: Permeation by potentially hazardous liquid chemical under conditions of continuous contact).* 14. **ISO 374-4:2019** *(Protective gloves against dangerous chemicals and micro-organisms. Determination of resistance to degradation by chemicals).* 15. **ISO 374-5:2016** *(Protective gloves against dangerous chemicals and microorganism – Part 5: Terminology and performance requirements for micro-organism risks)* 16. **ISO 13485:2016** *(Medical device Quality management system — Requirements for regulatory purposes).* 17. **ISO 14001:2015** *(Environmental Management System – Requirements with guidance for use).* 18. **ISO 14971:2019** *(Medical devices — Application of risk management to medical devices)* 19. **MEDDEV 2.7.1, Rev 4** *(Guidelines on Medical Devices / Clinical Evaluation: A guide for manufacturers and Notified Bodies).* 20. **ISO 15223-1:2016** *(Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements).* 21. **21 CFR 177.2600** *(Rubber articles intended for repeated use).*

The ICONIC MEDICARE SDN BHD declares that the above-mentioned products meet the provision of the following EU legislation Medical Devices Regulation (EU) 2017/745.

COMPANY REPRESENTATIVE: ***Tan Cho Chuan***

TITLE: ***QA Director*** SIGNATURE:

PLACE: ***Malaysia*** DATE: **5/4/2022**