EU MDR DECLARATION OF CONFORMITY

Declaration of Conformity

For the Sterile, Single Use Latex Surgical Gloves

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	**Sterile, Single Use Latex Surgical Gloves (Pre-Powder & Powder Free)**
Legal Manufacturer: (Name on Label)	**SWEAR HEALTHCARE PVT. LTD.** F-373 & 374, RIICO Growth Centre Extension, Dholpur-328001 (Rajasthan) (INDIA)
Manufacturers SRN:	IN-MF-000035426
Basic UDI-DI:	89043733LSG4H
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The sterile, surgical gloves are intended to act as a protective barrier between the patient and health care worker during invasive surgeries and also to facilitate general hand hygiene.
MDR Classification:	Class IIa, Rule 6
Notified Body:	Intertek Medical Notified Body AB, Sweden (NB 2862)
EC Certificate:	28620215480
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	**MT-AR-000000234**
Medical Device Regulation Assessment Route:	Conformity assessment based on Annexes IX of the EU MDR 2017/745.

Name	Gagan Deep Singh	**Position**	Manager QA & RA, PRRC		
Signature		**Date**	17.02.2026	**Place of Issue**	Dholpur (Rajasthan) (INDIA)
Name	Sanjeev Gaur	**Signature**			
Position	Director				

SWEAR HEALTHCARE PVT. LTD. DHOLPUR

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European harmonized and non-harmonized standards:

STANDARDS

S. No.	Description of Standard	Standard Reference
1	Medical Gloves for Single Use – Part-1 : Requirements and testing for freedom from holes.	EN 455-1:2020+A1:2022
2	Medical Gloves for Single Use – Part-2 : Requirements and testing for Physical Properties.	EN 455-2:2015
3	Medical Gloves for Single Use – Part-3 : Requirements and testing for biological evaluation.	EN 455-3:2023
4	Medical Gloves for Single Use – Part-4 : Requirements and testing for shelf life determination.	EN 455-4:2009
5	Single-use sterile rubber surgical gloves - Specification	ISO 10282 : 2023
6	Disposable Surgical Rubber Gloves - Specification	IS 13422 : 2024
7	Methods of Test for Vulcanized Rubber –Part 1- Determination of Tensile Strass-Strain Properties.	IS 3400 (Part-1)-2012 ,ISO 37 (2011)
8	Methods of Test for Vulcanized Rubber –Part 4- Accelerated Aging and Heat Resistance.	IS 3400 (Part-4)-2012 ISO 188 (2011)
9	Standard Specification for Rubber Concentrated, Ammonia Preserved, Creamed and Centrifuged Natural Latex.	D 1076-02
10	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers – Tension	D 412-06a
11	Standard Practise for Determination of expiration dating for Medical Gloves.	D7160-16
12	Sterilization of health care products-Ethylene oxide Part 1: Requirements for development, Validation and routine control of sterilization process for medical devices.	EN ISO 11135:2014/A1:2019
13	Sterilization of health care products –BIs, Part-1 (General Requirements).	EN ISO 11138-1:2017
14	Sterilization of health care products –Bis, Part-2 (Bis for EO Stl Process).	EN ISO 11138-2:2017
15	Sterilization of Medical Devices-Microbiological Methods Part-1 Determination of population of micro-organisms on products.	EN ISO 11737-1:2018/A1:2021
16	Sterilization of Medical Devices- Microbiological Methods Part-2-Tests of Sterility performed in the Validation of a Sterilization Process.	EN ISO 11737-2:2020
17	Water for analytical laboratory use – Specification and test methods.	ISO 3696 : 1987
18	Packaging for terminally sterilized medical devices Part 1 : Requirements for materials, sterile barrier systems & packaging systems	EN ISO 11607-1:2020 EN ISO 11607-1:2020/A1:2023
19	Packaging for terminally sterilized medical devices Part 2 : Validation requirements for forming, sealing & assembly processes	EN ISO 11607-2:2020 EN ISO 11607-2:2020/A1:2023
20	Packaging-Label material-Required information for ordering and specifying self-adhesive labels	ISO / TS 18614 : 2016
21	Medical devices – Application of risk management to medical devices.	EN ISO 14971 : 2019
22	Graphical symbols for use in the labelling of medical devices.	EN ISO 15223-1: 2021
23	Biological Evaluation of Medical Devices- Part 1 : Evaluation & Testing within a Risk Management Process.	EN ISO 10993-1:2020
24	Biological Evaluation of Medical Devices- Part 5 : Tests for *in vitro* cytotoxicity.	EN ISO 10993-5 : 2009
25	Biological Evaluation of Medical Devices- Part 7: Ethylene oxide sterilization residuals.	EN ISO 10993-7 : 2008 / AC : 2009

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S. No.	Description of Standard	Standard Reference
26	Biological Evaluation of Medical Devices-Part 10: Tests for irritation & skin sensitization. (Guidelines)	EN ISO 10993-10:2023
27	Biological evaluation of medical devices — Part 23: Tests for irritation	EN ISO 10993-23 : 2021
28	Biological Evaluation of Medical Devices- Part 12 : Sample preparation and reference materials. (Guidelines)	EN ISO 10993-12 : 2021
29	Biological Evaluation of Medical Devices- Part 17 : Establishment of allowable limit of leachable, Substances	EN ISO 10993-17 : 2023
30	Biological Evaluation of Medical Devices- Part 18 : Chemical Characterization of materials. (Guidelines)	EN ISO 10993-18 : 2020
31	Information Supplied by the Manufacturer of medical devices	EN ISO 20417 : 2021
32	Medical Devices – Quality Management Systems- Requirements for regulatory purposes.	EN ISO 13485 : 2016 EN ISO 13485:2016/A11:2021
33	Sampling Procedure for Inspection by Attributes Part 1-Sampling schemes indexed by Acceptance Quality Limit (AQL) for Lot-by-Lot Inspection	ISO 2859 – 1 : 1999
34	Indian Pharmacopeia	IP-2018
35	Clean Rooms & Associated Controlled Environments- Part-1 : Classification of Air Cleanliness by particle concentration	ISO 14644 – 1 : 2015
36	Clean Rooms & Associated Controlled Environments- Part-2 : Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.	ISO 14644 – 2 : 2015
37	Clean Rooms & Associated Controlled Environments- Part-3 : Test Methods	ISO 14644 – 3 : 2019
38	Clean Rooms & Associated Controlled Environments- Part-4 : Design, Construction & Start-up	ISO 14644 – 4 : 2001
39	Clean Rooms & Associated Controlled Environments- Part-5 : Operations	ISO 14644 – 5 : 2004
40	Cleanrooms & Associated Controlled Environments Part-6 Vocabulary	ISO 14644-6 : 2007
41	Cleanrooms & Associated Controlled Environments Part-7, Separative devices	ISO 14644-7 : 2004
42	Cleanrooms & Associated Controlled Environments Part-8 , Classification of air cleanliness by chemical concentration(ACC)	ISO 14644-8:2013
43	Cleanrooms & Associated Controlled Environments- Bio-contamination Control Part-1 : General Principles & Methods	ISO 14698 – 1 : 2003
44	Medical Devices – Application of Usability Engineering to Medical Devices	EN 62366-1 : 2015

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Appendix II – Product Listing/Schedule

Catalogue Ref. Number	Device Name & Size	Risk Class	EMDN Code	Basic UDI
LSG01	**STERILE, SINGLE USE LATEX SURGICAL GLOVES, POWDERED** Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 Brand-Medicmile, MyTouch, SWEAR	Class IIa	T010101	89043733LSG4H
LSG02	**STERILE, SINGLE USE LATEX SURGICAL GLOVES, POWDER FREE** Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 Brand- Medicmile Plus, MyTouch, SWEAR	Class IIa	T010101	89043733LSG4H

Version History

Issue / Version	Revision No.	Compiled by	Date	Description	Signature
1.0	00	Gagan Deep Singh	02.05.2023	First Issue	
1.0	01	Gagan Deep Singh	21.08.2023	Intended Purpose, EC Certificate No., Place of Issue, Details of the person who will sign the DoC, Variants Details.	
1.0	02	Gagan Deep Singh	01.10.2023	List of Standards has been revised for updated standards.	
1.0	03	Gagan Deep Singh	01.09.2025	(1)- EC MDR QMS Certificate received. (2)- List of Standards has been revised for updated standards.	
1.0	04	Gagan Deep Singh	17.02.2026	(1)- EU MDR Surveillance Audit-1 finding on alignment of Reference Numbers. (2)- List of Standards has been revised for updated standards.	