

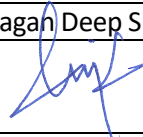
EU MDR DECLARATION OF CONFORMITY

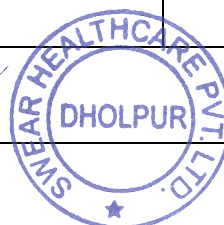
Declaration of Conformity for the Latex Examination Gloves

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:	LATEX EXAMINATION GLOVES (PRE-POWDERED AND 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:	89043733LEXGUZ
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The primary purpose of surgical gloves is to act as a protective barrier to prevent the possible transmission of diseases between healthcare professionals and patients during surgical and examination procedures.
MDR Classification:	Class I, Rule 5 (Non-sterile and Non-measuring Devices)
Notified Body:	Not Applicable for Class I
QMS Certificate:	0121089 ; Validity: 09.01.2028
EU Authorised Representative:	ADVENA LIMITED Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Conformity assessment based on EU Declaration of conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name	Gagan Deep Singh	Position	Manager QA & RA, PRRC		
Signature		Date	02.03.2026	Place of Issue	Dholpur (Rajasthan) (INDIA)
Name	Sanjeev Gaur	Signature			
Position	Director				



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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

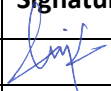
No	Standard/CS/Document Name	Description
1.	2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
2.	EN ISO 13485:2016+A11:2021	Medical Devices - Quality Management Systems-Requirements for regulatory purposes.
3.	EN ISO 14971:2019+A11:2021	Medical device - Application of risk management to medical device.
4.	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied : General requirements.
5.	EN ISO 20417 : 2021	Information Supplied by the Manufacturer of medical devices
6.	EN 455-1 : 2020	Medical Gloves for Single Use – Part-1 : Requirements and testing for freedom from holes.
7.	BS EN 455-2 : 2015	Medical Gloves for Single Use – Part-2 : Requirements and testing for Physical Properties.
8.	BS EN 455-3 : 2015	Medical Gloves for Single Use – Part-3 : Requirements and testing for biological evaluation.
9.	BS EN 455-4 : 2009	Medical Gloves for Single Use – Part-4 : Requirements and testing for shelf life determination.
10.	ISO 2859-1:1999	Sampling procedures for inspection by attributes – Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
11.	EN ISO 10993-1:2018	Biological Evaluation of Medical Devices- Part 1 : Evaluation & Testing within a Risk Management Process.
12.	EN ISO 10993-5 : 2009	Biological Evaluation of Medical Devices- Part 5 : Tests for <i>in vitro</i> cytotoxicity.
13.	ISO 10993-10 : 2010	Biological Evaluation of Medical Devices-Part 10: Tests for irritation & skin sensitization. (Guidelines)
14.	EN ISO 10993-12 : 2012	Biological Evaluation of Medical Devices- Part 12: Sample preparation and reference materials. (Guidelines)
15.	ISO 10993-23 : 2021	Biological evaluation of medical devices- Part 23: Tests for irritation

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Appendix II – Product Listing/Schedule

Catalogue Ref. Number	Device Name	Risk Class	EMDN Code	UDI-DI
LEXG01	Latex Examination Gloves, Pre-powdered, Size-Extra Small, Small, Medium, Large, Extra Large Brand- Mytouch, Swear, Medicmile	Class I (Non-sterile)	T010201	89043733LEXGUZ
LEXG02	Latex Examination Gloves, Powder Free, Size-Extra Small, Small, Medium, Large, Extra Large Brand- Mytouch, Swear, Medicmile	Class I (Non-sterile)	T010201	89043733LEXGUZ

Version History

Version	Revision No.	Compiled by	Date	Description	Signature
1.0	00	Gagan Deep Singh	01.01.2023	First Issue	
1.0	01	Gagan Deep Singh	02.03.2026	EU MDR Surveillance Audit finding on alignment of Reference Numbers.	