



EU Declaration of Conformity **(EU 2016/425 Personal Protective Equipment Regulation)**

1. Product Description:

Name of the Product: Sterile Latex Surgical Gloves – Powder Free

Brand Name/Trademark: DR. GLOVE

Variants: Size(s) – 6.0,6.5,7.0,7.5,8.0,8.5 and 9.0

PPE Category: Category III (Type C)

Conformity Assessment: Module D (EU Type-Examination)

Basic UDI-DI: 890615299LSG-PF-E72

EMDN Code: T01010102 Surgical Gloves, Latex, Non-Powdered

Sterilization Method: ETO sterilization method

2. Name and address of the manufacturer & Authorized Representative:

Manufacturer Address:

Vijayalakshmi Health & Surgicals Private Limited

Regd Office: Plot No.406, APIIC Growth Center, Gundlapalli (V), Maddipadu (M), Ongole, Prakasam Dist.-523 211, Andhra Pradesh, India. Ph.: +91 91 8592-221999. E-mail: info@vlhsglove.com, Web:

www.vlhsglove.com.

SRN Number: IN.MF.000019966

EU Authorized Representative Address:

CMC Medical Devices & Drugs S.L.

C/ Horacio Lengo N°18, CP29006, Málaga, Spain. Contact No: +34 951214054

www.cmcmedicaldevices.com

SRN Number: ES.AR.000000293

3. Intended use:

The Sterile Latex Surgical Gloves - Powder Free are intended to prevent contamination of the patient during invasive procedures and the user to protect their hand from exposure to potentially infectious materials.

4. Declaration of conformity:

We hereby under our sole responsibility declare that the above-mentioned product meets the provisions of the conformity assessment procedure described in Annex IX of Regulation EU declaration of conformity in these PPE Guidelines relate only to Regulation (EU) 2016/425 (Annex V & Annex VIII), applicable harmonized standards, and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.

VIJAYALAKSHMI HEALTH & SURGICALS PRIVATE LIMITED

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5. References to the relevant harmonized standards used,

Conformity with the provisions of module B of the regulation (EU) 2016/425 personal protective equipment and with the national standard transposing harmonized standard(S) technical specification based on EN ISO 374 -1 : 2016+A1:2018, EN ISO 374- 2 : 2019, EN ISO 374 - 4 : 2019, EN 16523 - 1 : 2015+A1:2018, EN 388- 2016+A1:2018, EN ISO 21420:2020 is identical to the PPE which is the subject of EU certification of conformity 0598/PPE.

6. Name of the Notified Body

Issued by Notify Body Address:

SGS Fimko Oy,

Takomotie 8, FI-00380 Helsinki, Finland

Notified Body No. 0598

Module B Certificate No:

EU Type-Examination Certificate Number: Regulation (EU) 2016/425, Module B: 0598/PPE/24/2473 Issue 1

Standard Reference:

EN ISO 374-1:2016 + A1:2018 (Protective gloves against chemicals and microorganisms) as a Type C glove.

EN ISO 374-5:2016 (Protective gloves against chemicals and micro-organisms) gloves protecting against bacteria, fungi (EN 374-2:2019 performance level 2) and virus (ISO16604:2004)

Module D Certificate No: IN24/00000576

7. Signed on behalf of VLHS Pvt Ltd:

Saravanan M

Sr. Manager QA/RA (PRRC)

(Done at Place: Plot No: 406, APIIC Growth Centre, Gundlapalli, Ongole, Prakasam District, Andhra Pradesh-523 211, India.

Date: 01.07.2026

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List of Applicable Regulations and Standards:

S.No.	Regulation/ Standard Number	Regulation/ Standard Name
1.	MDR (EU) 2017/745	Medical Device Regulation
2.	PPE (EU) 2016/425	Personal Protective Equipment Regulation
3.	EN ISO 13485: 2016 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
4.	EN ISO 14971: 2019 +A11 2021	Medical devices - application of risk management to medical devices
5.	EN 455-1: 2020 +A1 2024	Requirements and testing for freedom from holes
6.	EN 455-2: 2024	Requirements and testing for physical properties
7.	EN 455-3: 2023	Requirements and testing for biological evaluation
8.	EN 455-4: 2009	Requirements and testing for shelf-life determination
9.	ASTM F1671: 2013	Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using phi-x174 bacteriophage penetration as a test system
10.	EN ISO 20417:2026	Medical devices – Information to be supplied by the manufacturer
11.	EN ISO 15223-1: 2021 +A1 2025	ISO 15223-1 Symbols to be used with information to be supplied by the manufacturer
12.	EN ISO 11135: 2014+A1 2019	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
13.	EN ISO 374-1: 2016+A1: 2018	Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks
14.	EN ISO 374-2: 2019	Protective gloves against dangerous chemicals and micro-organisms - Part 2: Determination of resistance to penetration
15.	EN ISO 374-4: 2019	Protective gloves against chemicals and micro-organisms - Part 4: Determination of resistance to degradation by chemicals
16.	EN ISO 374-5: 2016	Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks
17.	EN 16523-1: 2015+A1: 2018	Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact
18.	EN ISO 21420: 2020	Protective gloves - General requirements and test methods

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