EU DECLARATION OF CONFORMITY

(Article 19/Annex IV as Per Regulation (EU) 2017/745)

Registered Office:	VIJAYALAKSHMI HEALTH & SURGICALS PRIVATE LIMITED Address: 406, APIIC Growth Center, Gundlapalli, Ongole, Prakasam District-523 211, Andhra Pradesh, India. Phone: +91 40 60122555 Email: coo@vlhsglove.com, QA@vlhsglove.com Website: https://www.vlhsglove.com/ Single Registration Number (SRN): IN-MF-000019966
European Representative:	CMC Medical Devices & Drugs S.L. Address: C/Horacio Lengo no 18, CP 29006, Malaga, Spain Phone: +34 951214054 Email: info@cmcmedicaldevices.com Website: www.cmcmedicaldevices.com SRN: ES-AR-000000293
Product Name:	Sterile Latex Surgical Gloves
Brand Name:	DR. GLOVE
Model/Variants:	Powder Free
Device Classification:	Class IIa, Rule 06 as per Annex VIII of MDR 2017/745
Basic UDI	
EMDN Code:	T01010102 - Surgical Gloves, Latex, Powder Free
MDA/MDN Code:	MDN 1204
MDS & MDT code(s):	MDS 1005 & MDT 2004, 2011
Sterilization Method:	Ethylene Oxide
Batch Number:	E.g. 221101
Conformity Assessment Route:	Declare the conformity of the above-mentioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annex IX chapter I and III, and including an assessment of the technical documentation as specified in Section 4 of that Annex IX according to Article 52 of Regulation (EU) 2017/745.

Size/Variant	Basic UDI-DI
6.0	890615299LSG-PF-E7Z
6.5	890615299LSG-PF-E7Z
7.0	890615299LSG-PF-E7Z
7.5	890615299LSG-PF-E7Z
8.0	890615299LSG-PF-E7Z
8.5	890615299LSG-PF-E7Z
9.0	890615299LSG-PF-E7Z

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Declaration:	We hereby under our sole responsibility declare that the above-mentioned product meets the provisions of the Medical Device Regulation EU 2017/745, applicable harmonized standards, and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.
Standards Applied:	**Harmonized Standards:** EN ISO 13485:2016/A11:2021, EN ISO 14971: 2019/A11:2021, EN ISO 20417:2026, EN ISO 15223-1:2021+A1 2025, EN 62366-1: 2015+A1:2020, EN ISO 10993-1:2025, EN ISO 10993-5:2009, EN ISO 10993-7: 2026, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021+A1 2025, EN ISO 11135: 2014/A1:2019, BS EN ISO 11138-2:2017, EN ISO 11737-1: 2018/A1:2021, EN ISO 11737-2:2020, EN ISO 11607-1:2020+A1 2023, EN ISO 11607-2:2020+A12023, BS EN 556-1: 2024, EN 455-1: 2020+A2:2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009 **Other Standards:** ISO 13485:2016, ISO 14971:2019, IEC 62366-1: 2015/AMD 1:2020, ISO 10993-1:2023, ISO 15223-1:2021, ISO 10993-5: 2009/A1:2019, ISO 10993-7: 2008/A1:2019, ISO 10993-10:2021, ISO 10993-11:2017, ISO 11737-1: 2018/A1: 2021, ISO 11737-2:2019, ISO 11607-1: 2019/A1:2023, ISO 11607-2: 2019/A1:2023, ISO 11135: 2014/A1:2018, ISO 10282:2023, ISO 2859-1:2026, IS 13422:2024, ASTM D 6124-06:2022, ASTM D 412: 16:2021, ASTM D5712-15:2020, ASTM D 3577:2023. **Guidelines:** MDCG 2021-24: Oct 2021, MDCG 2020-5:2020, MDCG 2020-6:2020, MDCG 2018-1 Rev.4: April 2021, MDCG 2020-7: April 2020, MDCG 2020-8: April 2020, MDCG 2022-21-Dec 2022, MDCG 2020-3 Rev 1-May 2023, MDCG 2024-2 Rev 01, January 2025, MDCG 2025-10 December 2025.
Notified Body:	DNV Product Assurance AS Address: Veritasveien 1, Høvik, 1363, Norway Website: www.dnv.com Notified Body No.: 2460
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EC Certificate(s):	Certificate no.: 10000510298-PA-NoMA-IND Initial certification date:18 October 2022 Valid Until: 18 October 2027
Place & Date of Issue:	Andhra Pradesh, India, 01.07.2026
Signature: Saravanan M PRRC/Sr.Manager QA (Name & Designation)	 On behalf of VLHS Pvt Ltd.