ST. MARYS RUBBERS PVT. LTD

ST MARYS RUBBERS PRIVATE LIMITED
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CIN : U25199KL2002PTC015698
GSTIN : 32AAHCS5763Q1ZP

DECLARATION OF CONFORMITY

Manufacturer	: St Marys Rubbers Pvt. Ltd XVII /401A, Thottamkavala, Vizhikkathode, Koovappally PO Kanjirappally, Kottayam,Kerala - 686518, India
SRN	: IN-MF-000008817
European Representative	: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem ,The Netherlands
SRN	: NL-AR-000000116
Device Name	: Sterile Latex Surgical Gloves Powder Free (Polymer coated)
Brand	: Medismart+, Mediten Plus, One Glove Plus, NEOMEX, POLYSEM, Medismart Premium Plus, Protex PF, Mediagni PF, Krutex, BROMED, CoreMed , IDA, SERIX EXPLORER PLUS, Dr.Mayer, Kaizmed, EUROGLOVES QLE, Medismart Premium Plus LOW PRO, P&Q, Integrity, LOGITOUCH, MG OriginPharma, Dr.Kelly, Antarcglove
Size	: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0
Device Intended use	: Sterile Latex Surgical Gloves Powder Free are intended for single use on one individual during single surgical procedure and to be worn once and then discarded. The gloves provide a protective barrier that reduces the risk of contamination and transmission of infectious agents, microorganisms, such as bacteria and viruses during medical procedures, particularly surgical interventions. The gloves are designed to protect the patient from cross-contamination and to to minimize the risk of the post-operative infections. The glove is made powder free by polymer coating method.
Device Classification	: Class IIa, Rule 06 as per MDCG 2021-24 & Annex VIII of MDR 2017/745
Basic UDI-DI	: 8908004933SLSPF2M5
EMDN Code	: T01010102 – Non-powdered latex surgical gloves
MDA/MDN Code	: MDN 1204
MDS & MDT code(s)	: MDS 1005, MDT 2011, MDT 2006, MDT 2008
Sterilization Method	: ETO sterilization/ Gamma Sterilization
Batch No	:
Conformity Assessment Route	: Annex IX
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.

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DECLARATION OF CONFORMITY

Standards Applied

: **Applicable Harmonized Standards**

EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021,EN ISO 20417:2021, EN ISO 15223-1:2021, EN 62366-1:2015+AC:2015+AC:2016+A1:2020,EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009,EN ISO 10993-10:2023, EN ISO 10993-11:2018,EN ISO 10993-12:2021,EN ISO 10993-23:2021,EN ISO 11135: 2014/A1:2019, EN ISO 11138-2:2017,EN ISO 11737-1:2018/A1:2021,EN ISO 11737-2:2020,EN ISO 11607-1:2020, EN ISO 11607-2:2020+A1:2023,EN 455-1:2020+A2: 2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2024

: **Applicable Other Standards**

ISO 13485:2016 , ISO 14971:2019, ISO 15223-1:2021, IEC 62366-1:2015/AMD1:2020 +COR1:2016, ISO 10993-1:2018, ISO 10993-5:2009,ISO 10993-7:2008/AMD1:2019+COR 1:2009, ISO 10993-10:2021, ISO 10993-11:2017,ISO 10993-12:2021, ISO 10993-23:2021, ISO 11135:2014/AMD 1: 2018, ISO 11138-2:2017, ISO 11737-1:2018/AMD1: 2021, ISO 11737-2:2019, ISO 11607-1:2019, ISO 11607-2:2019, ISO 10282:2023, ASTM D 3577-19(2023), ASTM F1980-21, ASTM D 6124-06:2022, ASTM D5712-15:2020,ASTM D4169 :2016, ASTM D999:2008,ISO 2233:2000, ISO 2248:1985, ISO 2247:2000, IS 7028-1:2002, IS 13422:1992, ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-4:2022

: **Guidelines**

MEDDEV 2.5/9 Rev 1, MEDDEV 2.7.1 Rev 4, MEDDEV 2.4/1 Rev 9, MEDDEV 2.12/2 Rev 2, MDR 2017/745,EU 2024/1860

Notified Body : DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Notified Body No : 2460

EC Certificate No. : C556189

Date & place of Issue : 06 February 2025, Høvik

Validity date : 05 February 2030

Place & date of Issue : Kanjirappally, 22.09.2025

Signature :

Name & Designation : Rony Emmanuel
Manager QA & PRRC

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