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 Powdered
Brand	: Medismart, Medistar, Mediten, One Glove, Medismart Premium, Mediagni
Size	: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5 & 9.0
Device Intended use	: Sterile Latex Surgical Gloves 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 minimize the risk of post-operative infections. The glove is pre powdered with absorbable corn starch for easy donning.
Basic UDI-DI	: 8908004933SLSPP1MZ
EMDN Code	: T01010101 – Surgical Gloves, Latex, Powdered
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	:
Product reference number	:

1. Medical Device details

Device Classification	: Class IIa, Rule 06 as per MDCG 2021-24 & Annex VIII of MDR 2017/745
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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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 10993-11:201,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

2. Personal Protective equipment Details

Device Classification : Personal Protective Equipment Category III as per regulation (EU) 2016/425
Conformity Assessment Route : EU type Examination (Module B) set out in Annexure V and conformity to type based on quality assurance of the production process (Module D) set out in Annexure VIII.
PPE Standards : EN ISO 374-1:2016 + A1:2018(type C), EN ISO 374-5:2016, EN ISO 374-2:2019,EN ISO 374-4:2019,EN 16523-1:2015+A1:2018,ISO 21420:2020,ISO 3071:2020,ISO 16604:2004

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DECLARATION OF CONFORMITY

Applicable Guidance Documents : EU 2016/425

Declaration : We declare under our sole responsibility that the above mentioned product complies with the essential requirements of PPE Regulation (EU) 2016/425. All Prior amendments are and as transposed into national laws.

Name of Notified Body& Address : SGS Fimko Oy
: Notiifed Body 0598, Takomotie 8, FI-00380 Helsinki, Finland

Notified Body Number : 0598

I. EU Type –Examination Certificate, Module B

Certificate No. : 0598/PPE/24/5610 Issue 1
Date & Place of Issue : 12 December 2024, SGS FIMKO Ltd
Validity Date : 12 December 2029

II. Module D certificate details

Certificate No. : IN22/00000837
Date & Place of Issue : 15 December 2022, SGS FIMKO Ltd
Validity Date : 15 December 2025

Place & date of Issue : Kanjirappally, 22.09.2025

Signature :

Name & Designation : Rony Emmanuel
Manager QA & PRRC

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