ST. MARYS RUBBERS PVT. LTD

ST MARYS RUBBERS PRIVATE LIMITED
Reg.Office Address:XVII/401A,Thottamkavala
Vizhikkathode, Koovappally P.O.
Kanjirappally, Kottayam
Kerala - 686518, India

Phone : +91 99953 39270
+91 94460 50270
Email : cs@stmarysrubbers.com
Web : www.stmarysrubbers.com
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, Medismart Premium Plus, Mediagni PF, MEDISMART PREMIUM PLUS LOW PRO
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.
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	:
Product reference number	:

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 13422:2024(ISO 10282:2023), 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

SMR

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/24/5612, 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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