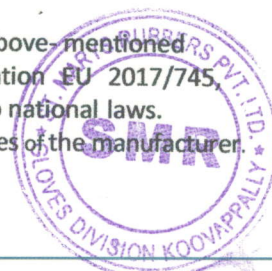


DECLARATION OF CONFORMITY

Manufacturer	: St Marys Rubbers Pvt. Ltd XVII /401A, Thottamkavala, Vizhikkathode, Koovappally PO Kanjirappally, Kottayam, Kerala- 686518, India
SRN	: IN-MF-000008817
European Representative SRN	: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem ,The Netherlands : NL-AR-000000116
Device Name Brand Size	: Sterile Latex Gynaecological Gloves Powder Free (Polymer coated) : Medismart +, SERIX EXPLORER OBGYN : 6.5,7.5,8.5
Device Intended use	: Sterile Latex Gynaecological Gloves Powder Free are intended for single use on one individual during single gynaecological and obstetrical procedures 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 gynaecological and obstetrical procedures. The gloves are designed to protect the patient from cross-contamination and to minimize the risk of the post-operative infections. The gloves are made powder free by polymer coating process.
Basic UDI-DI EMDN Code MDA/MDN Code MDS & MDT code(s) Sterilization Method Batch No Product reference number	: 8908004933SLGPF2JH : T01010102 – Non-powdered latex surgical gloves : MDN 1204 : MDS 1005, MDT 2011, MDT 2006, MDT 2008 : ETO sterilization/Gamma Sterilization : :
Medical Device details	
Device Classification Conformity Assessment Route	: Class IIa, Rule 06 as per MDCG 2021-24 & Annex VIII of MDR 2017/745 : 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.



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 10993-11:201, 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

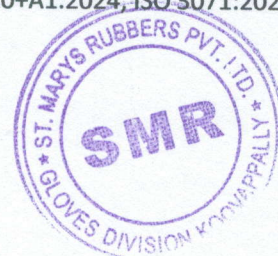
Conformity Assessment

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+A1:2024, ISO 3071:2020, ISO 16604:2004



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/22/3694, Issue 1
Date & Place of Issue : 06 September 2022, SGS FIMKO Ltd
Validity Date : 06 September 2027

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

