ST. MARYS RUBBERS PVT. LTD

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

DECLARATION OF CONFORMITY

Application of European Union Council Directive 93/42/EEC as amended by 2007/47/EC

Manufacturer	: St Marys Rubbers Pvt. Ltd. XVII /401A, Thottamkavala, Vizhikkathode, Koovappally PO, Kanjirappally, Kottayam - 686518, India
SRN	: IN-MF-000008817
European Union Authorized Representative	: Emergo Europe ,Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	: NL-AR-000000116
Product	: Sterile Latex Surgical Gloves Powder Free (Polymer coated)
Basic UDI-DI	: 8908004933SLSPF2M5
Brand	: Medismart Premium Plus
Batch No	:
Size	: 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0

1. Medical Device details

Device Classification	: Class IIa as per Rule 6, Annex IX of Council Directive 93/42/EEC
Conformity Assessment Route	: Article 11.3(a) and Annex II excluding section 4
Standards Applied	**: Applicable Harmonized Standards** EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN ISO 20417:2021,EN ISO15223-1:2021, 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 10993-10:2013, 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, EN 455-1:2020+A1:2022, EN 455-2:2024, EN 455-3:2015, EN 455-4:2009, EN 556-1:2001/AC:2006 **Applicable Other Standards** ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, IEC 62366-1:2015/AMD 1:2020+COR1:2016,ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008/AMD 1:2019+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/AMD 1: 2021, ISO 11737-2:2019, ISO 11607-1:2019,ISO 11607-2:2019, ISO 10282:2023, ASTM D3577-19, ASTM F1980-21, ASTM D6124-06:2017, ASTM D5712-15:2020, IS 7028-1:2002,ASTM D4169:2016, ASTM D999:2008, ISO 2233:2000, ISO 2248:1985, ISO 2247:2000 , IS 13422:1992,ISO 14644-12015,ISO 14644-2:2015,ISO 14644-4:2022
Applicable Guidance Documents	: MEDDEV 2.5/9 Rev 1, MDD 93/42/EEC as amended, MEDDEV 2.7.1 Rev 4, MEDDEV 2.4/1 Rev 9, MEDDEV 2.12/2 Rev 2,MDR 2017/745,EU 2023/607,MDCG 2020-3, rev 1
Notified Body name & address	:DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway
Notified Body	: 2460

ST MARYS RUBBERS PVT. LTD. SMR GLOVES DIVISION KOOVAPPALLY

medismart | medismart | MEDISTAR | medismart PREMIUM | medismart PREMIUM PLUS | Soteria | medismart GYNAECOLOGY | Setia
PREMIUM QUALITY LATEX SURGICAL GYNAECOLOGICAL AND EXAMINATION GLOVES

13044

DECLARATION OF CONFORMITY

Application of European Union Council Directive 93/42/EEC as amended by 2007/47/EC

EC Certificate No	: 9877-2017-CE-IND-NA-PS Rev.4.0
Date & place of Issue	: 26 April 2021, Høvik
Validity date	: 31 December 2028
Notified Body conformation letter Reference	: C685853

2. Personal Protective equipment Details

Device Classification	: Personal Protective Equipment Category III as per regulation (EU) 2016/425
PPE Standards	: EN ISO 374-1:2016 + A1:2018, 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
Applicable Guidance Documents	: EU 2016/425
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/22/3698, Issue 1
Date & Place of Issue	: 07 September 2022, SGS FIMKO Ltd
Validity Date	: 07 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

We declare under our sole responsibility that the above mentioned product complies with the essential requirements of EC Directive 93/42/EEC, Annex IX, Class IIa, Rule 6 , EU 2023/607 and PPE Regulation (EU) 2016/425. All Prior amendments are and as transposed into national laws.

Signed on the behalf of the manufacturer:

Anjali Vinod
Manager QA

Date: 07.08.2024
Place: Kanjirappally

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