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 Union Authorized Representative	: Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SRN	: NL-AR-000000116
Product	: Sterile Latex Examination Gloves Powder Free
Brand	: Smartex Plus
Size	: XS, S, M, L, XL
Intended Use	: Sterile Latex Examination gloves are intended for single use on one individual during single procedure. 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 examinations, diagnostic and therapeutic procedures. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures through body orifices.
Device Classification	: Class Is, Rule 05 as per MDCG 2021-24 & Annex VIII of MDR 2017/745
Basic UDI-DI	: 8908004933SLEPF2J3
EMDN Code	:T010201: Latex examination / treatment gloves
MDA/MDN Code	: MDN 1204
MDS & MDT code(s)	: MDS 1005, MDT 2011, MDT 2006, MDT 2008
Sterilization Method	: ETO sterilization
Batch No	:

Medical Device details

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 manufacture.

ST MARYS RUBBERS PVT. LTD. SMR GLOVES DIVISION KOOVAPPALLY

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 10993-12:2021, 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+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/AM1:2020+COR1:2016,ISO10993-1:2018,ISO 10993-5:2009,ISO10993-7:2008/AMD1: 2019+COR 1:2009, ISO 10993-10:2021,ISO 10993-12:2021, ISO 10993-23:2021, IS 11135: 2014/AMD 1: 2018, ISO 11138-2:2017, ISO 11737-1:2018/AMD 1: 2021, IS11737-2:2019, ISO 11193-1:2020, ISO 11607-1:2019, ISO 11607-2:2019, IS 7028-1:2002,ASTM D4169:2016, ASTM D999:2008, ISO 2233:2000, ISO 2248:1985, IS 2247:2000,ASTM F1980-21 ASTM D 6124-06:2022, ASTM D5712-15:2020, ASTM D 3578-19:2019, 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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