

DECLARATION OF CONFORMITY

Manufacturer	St Marys Rubbers Pvt. Ltd XVII /401A, Thottamkavala, Vizhikkathode, Koovappally PO Kanjirappally, Kottayam - 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 Gynaecological Gloves Powdered
Brand	: Medismart
Size	: 6.5, 7.5, 8.5
Device Intended use	: Sterile Latex Gynaecological Gloves Powdered 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-procedural infections. The glove is pre powdered with absorbable corn starch for easy donning.
Device Classification	: Class IIa, Rule 06 as per MDCG 2021-24 & Annex VIII of MDR 2017/745
Basic UDI-DI	: 8908004933SLGPP1KD
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
Batch No	:
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.



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 10993-11:2021, 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+COR1:2009, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-12:2021, ISO 10993-23:2021, ISO 11135:2014/AMD1:2018, 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 Certificates(s)

: C556189

Place & date of Issue

: Kanjirappally, 08.09.2025

Signature

:  

Name & Designation

: Rony Emmanuel
Manager QA & PRRC