

## DECLARATION OF CONFORMITY

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer                   | : St Marys Rubbers Pvt. Ltd<br>XVII /401A, Thottamkavala, Vizhikkathode, Koovappally PO<br>Kanjirappally, Kottayam, Kerala - 686518, India                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| SRN                            | : IN-MF-000008817                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| European Representative<br>SRN | : Emergo Europe, Westervoortsedijk 60, 6827 AT Arnhem ,The Netherlands<br>: NL-AR-000000116                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Device Name                    | : Sterile Latex Surgical Gloves Powder Free (Polymer coated)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Brand                          | : Medismart Premium Plus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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.<br><br>The gloves are designed to protect the patient from cross-contamination and to minimize the risk of the post-operative infections. The glove is made powder free by polymer coating method. |
| Device Classification          | : Class IIa, Rule 06 as per MDCG 2021-24 & Annex VIII of MDR 2017/745                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 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                       | : 2460                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Conformity Assessment          | : 06 February 2025, HANIK                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 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 10993-11:2018, 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+A1:2023, EN 455-1:2020+A2: 2024, EN 455-2:2024, EN 455-3:2023, EN 455-4:2009, EN 556-1:2024, EN ISO 11137-1:2015/A2:2019, EN ISO 11137-2: 2015/A1:2023, EN ISO 11137-3:2017

#### : 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/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, ISO 11137-1:2006/A2:2018, ISO 11137-2:2013/A1:2022, ISO 11137-3 : 2017

#### : 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, 08.07.2025

### Signature

:

### Name & Designation

: Rony Emmanuel  
Manager QA & PRRC

