

Doc No: F/QA/51
Rev No: 00
Rev Date: 06.08.2024

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 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 10993-10:2013, 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 14644-1:2015, 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



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
: Notified 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

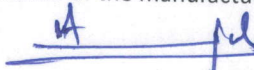
Certificate No. : IN22/00000837
Date & Place of Issue : 15 December 2022, SGS FIMKO Ltd
Validity Date : 15 December 2025

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.

Date: 07.08.2024
Place: Kanjirappally



Signed on the behalf of the manufacturer:


Anjali Vinod
Manager QA