ST. MARYS RUBBERS PVT. LTD

ST MARYS RUBBERS PRIVATE LIMITED
Reg.Office Address:XVII/401A,Thottamkavala
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CIN : U25199KL2002PTC015698

Doc No: F/QA/32
Issue No, Date: 01, 11.09.2018
Rev No, Date: 04, 30.11.2020

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
European Union Authorized Representative	: Emergo Europe BV, Prinsessegracht 20, 2514 AP The Hague, The Netherlands
Product	: Sterile latex surgical gloves, powdered
Brand	: Medismart
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	: EN ISO 13485 : 2016 , EN ISO 14971 : 2012, EN455-1 : 2000,EN 455-2:2009+A2:2013 EN 455-3 : 2006, EN 455-4 : 2009, EN ISO 15223-1:2016, EN ISO 10993-1 : 2009, EN ISO 10993-5 : 2009, EN ISO 10993-7 : 2008, ISO 10993-10 : 2010,ISO 11135-1:2014, EN ISO 11138-2 : 2009, EN ISO 11737-1 : 2006 , EN ISO 11737-2 : 2009 , EN ISO 11607-1 : 2009, EN ISO 11607-2 :2006 , EN 1041:2008 , ISO 10993-11:2017, EN 62366:2008
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, NB- MED /2.12/Rec 1
Notified Body name & address	: DNV GL Presafe AS Veritasveien 3, N- 1363 Høvik, Norway
Notified Body	: 2460
EC Certificate No.	: 9877-2017-CE-IND-NA-PS Rev. 4.0
Date & Place of Issue	: 26 April 2021, Hovik
Validity Date	: 27 May 2024

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. All Prior amendments are and as transposed into national laws
This Declaration of Conformity is valid until 27 May 2024, EC certificate validity date.

Authorized Signatory

Anjali Vinod
Manager QA

Date : 14.05.2021
Place: Kanjirappally

ST.MARY'S RUBBERS PVT.LTD
SMR
GLOVES DIVISION,KOOVAPPALLY