EU Declaration of Conformity
to the 2017/745 Medical Device Regulation
2016/425 Personal Protective Equipment Regulation

We, GMT International SUPER GLOVES Ptd. Ltd., declare under our sole responsibility that the product stated below meets all provisions of the
Medical Device Regulation (EU) 2017/745
and
Personal Protective Equipment Regulation (EU) 2016/425

Manufacturer:	GMT International SUPER GLOVES Ptd. Ltd.
Address:	51, Goldhill Plaza 07-10/11 308900 Singapore
SRN:	SG-MF-000022815

Product Name:
GMT SUPER GLOVES Nitrile Examination Gloves Powder Free Offline Chlorination, Non-Sterile

Product Group Code:	NO026
Basic UDI-DI:	888501870NO026J2
Intended Purpose:	
The GMT SUPER GLOVES are non-sterile examination gloves. These are disposable medical devices intended for medical purposes, i.e. to be worn by a healthcare professional on his hands or fingers to prevent contamination between patient and healthcare professional, while performing medical activities except surgically invasive procedures. The medical examination can be either on intact skin, or within natural body orifices or in contact with body fluids.	

Device Classification:	Class I under rule 5 according to Annex VIII
CE marking first applied:	May 2021
GMDN code and term:	56286 Nitrile examination/treatment glove, non - powdered, non-antimicrobial
EMDN/CND:	T01020204 (Examination/ Treatment Gloves, Nitrile)
Conformity Assessment Route: (As per MDR 2017/745)	Annexes II and III

GMT International Super Gloves Pte. Ltd.
51, Goldhill Plaza 07-10/11, 308900 Singapore **T** +65 6549 7245 *Registration N UEN: 201802205H*
E customer-service@gmt-supergloves.com
www.gmt-supergloves.com

Authorized EC-Representative for GMT:	Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands
SRN:	NL-AR-000000116

This Declaration of Conformity is issued on the basis of fulfilment the requirements of Annex IV of the Medical Device Regulation (EU) 2017/745 with:

- Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745

This Declaration of Conformity is also issued on the basis of fulfilment of the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III:

- The conformity is based on quality assurance of the production process under the surveillance of the notified body number 2777 by SATRA Technology Europe Ltd. (Module D).
- The EU-Type Examination Certificate number 2777/11578-02{/}E27-01.
- Quality System Certified to EN ISO 13485:2016 valid until 02/05/2027, and EN ISO 9001:2015 valid until 19/05/2027.

List of Applicable Regulations and Standards

1. MDR (EU)2017/745
2. PPE (EU) 2016/425
3. EN ISO 13485:2016
4. EN ISO 9001:2015
5. EN ISO 14971:2019
6. EN ISO 20417:2021
7. EN ISO 15223-1:2021
8. EN 455-1:2020
9. EN 455-2:2015
10. EN 455-3:2015
11. EN 455-4:2009,
12. ISO 10993-1:2018
13. ISO 10993-5:2009
14. ISO 10993-10:2010
15. EN ISO 21420:2020
16. EN ISO 374-1:2016+A1:2018
17. EN ISO 374-2: 2019
18. EN ISO 374-4:2019
19. EN ISO 374-5:2019
20. EN 16523-1: 2015+A1:2018

GMT INTERNATIONAL SUPER GLOVES PTE. LTD. Co. Reg. No. 201802205H

Name: Sofia Tzavara
Position: Quality Management Representative
Date: 24 March 2024
Place of issue of the EU Declaration of Conformity:
GMT International SUPER GLOVES Ptd. Ltd. 51, Goldhill Plaza 07-10/11 308900 Singapore

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Annex

(Product Description)

Trade name	Product Description	Product Reference code
GMT SUPER GLOVES	Nitrile Examination Gloves Powder Free	NO026

Color	Device Model
Black	NO-MD-026-BL-35
Violet Blue	NO-MD-026-VB-32
	NO-MD-026-VB-35
	NO-MD-026-VB-30
Dark Blue	NO-MD-026-DB-30

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