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 medical device 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 Online Chlorination, Non-Sterile

Product Group Code: NO003
Basic UDI-DI: 888501870NO003HN
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 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

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 the requirements of the Personal Protective Equipment Regulation (EU) 2016/425 for Category III:

- The conformity based on quality assurance of the production process under surveillance of the notified body number 2777 by SATRA Technology Europe Ltd. (Module D).
- The EU-Type Examination Certificate number 2777/17447-03/E15-01

List of Applicable Regulations and Standards

1. MDR (EU)2017/745
2. PPE (EU) 2016/425
3. ISO 13485:2016
4. 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 10993-10:2010
14. ISO 10993-11:2017
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: Mr. George Kalaitzakis
Position: C.E.O.
Date: 12 December 2023
Place of issue of the EU Declaration of Conformity:
GMT International SUPER GLOVES Ptd. Ltd.
51, Goldhill Plaza 07-10/11 308900 Singapore