

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: Annexes II and III

(As per MDR 2017/745)

Authorized EC-Representative for GMT:

Emergo Europe B.V. Westervoortsedijk 60 6827 AT Arnhem The Netherlands

SRN: NL-AR-000000116

GMT International Super Gloves Pte. Ltd.

51, Goldhill Plaza 07-10/11, 308900 Singapore **T** +65 6549 7245 *Registration N UEN*: 201802205H

E <u>customer-service@gmt-supergloves.com</u>

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:

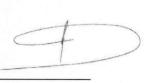
 Availability of technical documentation per Annex II and Annex III of the Medical Device Regulation (EU) 2017/745

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
- EN ISO 14971:2019
- 6. EN ISO 20417:2021
- 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





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

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