Issued to:



Notified Body: 2777

DCK GRUP İÇ DIŞ TİCARET MEDİKAL LTD.ŞTİ.
MACUN MAH. BATI BULV. ATB İŞ MERKEZİ E BLOK 1/108
YENİMAHALLE
Ankara
06374
Turkey

Module C2 Certificate

This is to confirm that the following product(s) have been found to conform to the applicable requirements of annex VII of the PPE Regulation (EU) 2016/425 - conformity to type based on Module C2 where a valid EU type examination certificate issued under module B of Regulation (EU) 2016/425 on Personal Protective Equipment also exists.

Module B Type Examination 2777/

Certificate:

2777/12717-03/E04-01

Product Group Reference(s): MASTERFUL

Disposable non sterile powder free nitrile examination glove, 4.5 mil

Product Type(s): Colour: Blue

EN ISO 374-1:2016+A1:2018 Type B

EN ISO 374-5:2016

Classification(s): EN ISO 374-4:2019

Test Report(s): CHM2010891 SPC2010893

STE Reference: STE2010519

Signed on behalf of SATRA Technology Europe Limited:

R Bay (85)

Rebecca Bayliss

Date of issue: 24/09/2024

Expiry date: 24/09/2025 age 1 of 2

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement.

Please note:

- 1. This product is classified as category III and as such CE Marking of production is reliant on current compliance with Regulation 2016/425 on Personal Protective Equipment.
- 2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
- 3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
- 4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
- 5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on the relevant module B certificate.
- 6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
- 7. Where results obtained are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
- 8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by the authorities.
- 9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
- 10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of Regulation 2016/425 on Personal Protective Equipment.