EUROTECH CERTIFICATION

Conformity Certificate

No. 3128 MDD 080/EU

This certificate applies for the product that specifications have detailed

Disposable Non Woven Medical Face Mask (Non-sterile, Type IIR)
(Class I not sterile or measuring via Annex IX Rule I)
Face masks being used for patient protection (MDD Class I)

Brand Name: MYFLON

And manufactured by the below company:

FELIKS PLASTIK LAMINASYON VE AMB. MALZ. SAN. VE TIC. LTD. STI. AS.

75. Yil Eskisehir Organize Sanayi Bolgesi 26 Cad. No: 9, 26110 Odunpazari/ Eskisehir/

TURKEY

The relevant directives and related standards declared by the company are as follows:

93/42/EEC and 2007/47/EC - Medical device directive

ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes
EN 14683:2019+AC:2019- Medical face masks - Requirements and test methods

By EUROTECH, this certificate has given as a Declaration Of Conformity in line with the directives stated in results of laboratory tests by Ekoteks Laboratuvar Testing (Acc. No: AB-0583-T) for Laboratory BFE, Microbial Cleanliness and Differential Pressure, dated as 25.08.2020, with report no 20028358 and the information declared by the company.

It does not mean that EUROTECH performs any supervision or control over the production of the products.

This certificate is not a Notified Body certificate, it was prepared only as a Declaration of Conformity as a result of the product inspection.

Product description, modifications, technical documentation, evaluation procedures and evaluation of products must be met by the company in accordance with the standard and directive requirements.

This certificate is issued on 20/09/2021 and valid until expiry date with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

CE

Original Issue Date: September 20, 2021

Expiry Date: September 20, 2022

Eurotech Certification

Herriotstraße 1 60528 Frankfurt am Main / Germany
eurotechcertification.com, email:info@eurotechcertification.com