

EU DECLARATION OF CONFORMITY

This Declaration of Conformity, issued under the sole responsibility of the manufacturer **En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş., Atatürk Mah. 31043 Sk. Kubat Apt. No: 8/B Mezitli / Mersin, Turkey** hereby declaring the following products.

Product Description: ENMED Surgical Masks

Model No	Ref No	Product Name
ENM-712	313101001	FFP2 Fold without valve
ENM-712-1	313101004	FFP2 Fold with valve
ENM-713	313101010	FFP3 Fold without valve
ENM-713-1	313101050	FFP3 Fold with valve

Regulation: PPE Regulation (EU) 2016/425 Annex 9

Manufacturer: En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.

EU Representative/Importer: TT Transporte & Logistik GmbH, Dieselstr. 6 in D-50354 Hürth

Head Office/Design Center: Atatürk Mah. 31043 Sk. Kubat Apt. No: 8/B Mezitli / Mersin Turkey

Mask Manufacturing Site: Karaduvar Mh. Serbest Bölge 7. Cad. No: 21 33020 Akdeniz Mersin/ Turkey

Based on the evaluation of test reports and internal quality control audit reports according to EN149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products shown above are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

European Union Regulation:

Medical Device Directive:

The model is/are in conformity with the provisions of the European Community Regulation (EU) 2016/425 (Personal Protective Equipment Regulation) and are thus CE marked. EN 149:2001 + A1:2009,

Conformity assessment procedure: N/A (self declaration)

Place / Date of Issue: Mersin, 24.11.2020

Signed by: Reşat Hamdi Yıldız
Company Owner

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EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ
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