

# 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

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

**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

## 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, 21.09.2020

Signed by: Reşat Hamdi Yıldız  
Company Owner

EN ECZA DEPOSU İLAÇ MEDİKAL  
ÖZEL SAĞLIK HİZM. A.Ş.

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ  
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