EU Declaration of Conformity

Regulation (EU) 2017/745

1. This EU Declaration of conformity refers to the following products:

Product Name	Model	Classification/Type	Reference Number	UDI
3 Ply Ultrasonic Procedure Mask (Type II-R) Blue	ENM- 313	Class I	313R01201	868243103313R01201Q9

2. Manufacturer's name and address is as below:

Company Name	En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş.
Address	Saray Mahallesi Gıdacılar Caddesi 3670 Ada 2 Parsel Kahramankazan ANKARA/ TURKEY
AB Authorized Representative	ENMED B.V.
Address	Oudeweg 109A 2031 CC Haarlem Amsterdam NETHERLANDS

3. The Conformity assessment according to the essential requirements has been done by Easepal according to

EU Community Legislation

En Ecza Deposu İlaç Medikal Özel Sağlık Hizmetleri İnşaat Taahhüt Ticaret A.Ş, declares that under our sole responsibility that the product above to which this declaration relates are in conformity with the following standards or other regulatory laws following the provisions of 2017/745 Medical Device Regulation.

Harmonised standart:

EN 14683:2019 Medical face masks. Requirements and test methods. Protective clothing, Classification systems, Performance, Performance testing, Biological hazards, Masks (protective clothing), Contamination, Surgical equipment, Occupational safety, Hygiene, Medical equipment, Environmental cleanliness, Permeability measurement.

Declaration Type: EC Certificate Nuvo Certification

This declaration is valid until: This certificate is initially issued on 16.11.2021 and will be valid for 1 years from the issue date.

Place and Date of Issue: Ankara / TURKEY **Date:** 16.11.2021 **Company Sign:** EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZM. A.Ş.

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ