



UNIVERSAL

CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1413

Respiratory protective devices, filtering half masks to protect against particles manufactured by

CARINE EUROPE GMBH

Ammanstrasse No:12 86167 Augsburg/GERMANY

CARINE EUROPE GMBH

Manufacturing Site I: Röntgen str. 40 86368 Gersthofen GERMANY

AYDAĞ TEDAVİ ve SAĞLIK HİZMETLERİ SAN. ve TİC. A.Ş

Manufacturing Site II: Orta Mah. Menderes Cad. No:7/3 K1 Bayrampaşa İstanbul TURKEY

are tested and evaluated according to

**EN 149:2001 + A1:2009 Respiratory Protective Devices -
Filtering Half Masks to Protect Against Particles -
Requirements, Testing, Marking**

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: Carine Medical, Model: CRM-P200

Filtering half mask

Classification: FFP2 NR

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**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **06/09/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



Verify the validity with the QR code

This certificate is re-issued on 19.01.2021 to include new manufacturing site.