

UNIVERSAL

CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163-PPE-1413/01

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

Continues to fulfil the requirements of

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

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No	Date	Issuing NB No
Carine Medical / CRM-P200	FFP2 NR	2163-PPE-1413	06.09.2020	2163

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.

This certificate is issued on 06/02/2021 and will be valid for one year, until 05/02/2022 if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163


Suat KACMAZ

UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

