

UNIVERSAL CERTIFICATION

NB 2163

CONFORMITY TO TYPE CERTIFICATE

Certificate No: 2163-PPE-1484/01

CARINE EUROPE GMBH

Ammannstrasse No:12 86167 Augsburg / GERMANY

Manufacturer:

Aydağ Tedavi ve Sağlık Hizmetleri Sanayi ve Ticaret A.Ş.
Orta Mah. Menderes Cad. No:7/3 K1 Bayrampaşa İstanbul TURKEY

continues to fulfil the requirements of

Personal Protective Equipment Regulation (EU) 2016/425 and applied standards EN ISO 13688:2013, ISO 14605:2005+A1:2009, EN 14126:2003 /AC:2004 based on the evaluation of test reports and internal quality control audit reports according to Module C2 (Annex VII) of PPE Regulation.

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

Brand Name and Model		EU Type Examination Certificate		
		Serial No.	Date	Issuing NB No.
Carine Medical	CRM-PCA-100	2163-PPE-1484	22.09.2020	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 **03/04/2021** and will be valid for one year, until **02/04/2022** 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

