



UNIVERSAL  
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1483

CARINE EUROPE GMBH

Ammann Strasse No:12 86167 Augsburg GERMANY

Manufacturer:

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

It is certified that the manufacturer's technical file (Dated 25.08.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment

Brand Name: Carine Medical, Model: CRM - IGA

Isolation gown manufactured from polypropylene non-woven fabric with partially ultrasonic welded and over lock seams, with belt. The gown is available in 5 nominal sizes.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)

EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited wear life clothing,

EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B

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 the below requirements;

- 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

This certificate is initially issued on 22/09/2020 and will be valid for 5 years from the issue date.



Suat KAÇMAZ  
UNIVERSAL CERTIFICATION  
Director



Verify the validity with the QR Code