Certificate Number: D-PPE20171075

PRODUCTION CONFORMITY TO TYPE CERTIFICATE

This is to certify that INSPEC International B.V., Notified Body 2849, has assessed the quality system of the manufacturer and deemed it to be in compliance with Annex VIII (Module D) of the Personal Protective Equipment Regulation (EU) 2016/425.

Manufacturer:
SPRO MEDICAL PRODUCTS (XIAMEN) CO., LTD
West of 1-5th Floor, No.139 Factory Bldg
TongAn Garden, TongAn Industry Area
Xiamen City
Fujian Province
China

Authorised Representative:
SPRO MEDICAL (EU) SP.Z O.O.
Ul. Tadeusza Kos'ciuszki
14/4,84-200
Wejherowo
Poland

The scope of the certification is for:

The manufacture of respiratory protective devices

as per the Product Type(s) and Site(s) listed on page 2.

This certificate, while valid, serves as authorisation to the manufacturer from INSPEC International B.V. to affix our notified body identification number, 2849, to each individual item of PPE that is in conformity with the type described in the type-examination certificates.

Date of initial certification: 18 May 2020
Date of current issue: 25 January 2022
Date of expiry: 18 May 2024

Certification Manager

PRODUCTS
RvA C 657

Product Types

The PPE produced under this quality system was designed taking into consideration the following standard(s) / technical specification(s):

Standard	Product type
EN149	Filtering half masks to protect against particles

The Type-examination certificate(s) number(s) for the PPE subject to our assessment of the quality system are detailed within internal INSPEC International B.V. documentation.

Sites

The quality system incorporates the following premise(s):

Site	Name / Physical Address
Primary office and Production location:	As per certificate holder address

Certificate Number: D-PPE20171075

Certificate amendment record

Date	Description
25/01/2022	Addition of Authorised Representative.
18/05/2021	Re-issued following re-assessment. Previous version was issued by NB0194.
18/05/2020	Initial Issue

Conditions attached to the issue of this certificate

1. The manufacturer / authorised representative shall undertake to fulfil the obligations arising out of the quality system, and of the Personal Protective Equipment Regulation (EU) 2016/425, Annex VIII, and with INSPEC's Regulations governing this Module.

2. The manufacturer / authorised representative shall inform INSPEC of any planned changes to the quality system, wherein INSPEC will proceed with evaluation of the proposals as per Annex VIII, 3.5.

3. For the certificate to remain valid audits and visits must be conducted, as per Annex VIII, 4.

4. The manufacturer may affix INSPEC's notified body identification number, 2849, to each PPE, and draw up a written EU declaration of conformity for each PPE model referencing this certificate and the Type-examination certificate(s) as per Annex VIII, 5.

5. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.

6. This certificate may be copied or reproduced by the certificate holder, complete and without omissions or additions, and in accordance with INSPEC's terms of business.