

PRODUCTION CONFORMITY TO TYPE CERTIFICATE

This is to certify that INSPEC International Limited, Notified Body 0194, 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

The scope of the certification is for:

The manufacture of respiratory protective devices

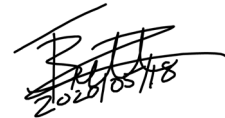
as per the Product Type(s) and Site(s) listed on page 2.

This certificate, while valid, serves as authorisation to the manufacturer from INSPEC International Ltd to affix our notified body identification number, 0194, 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: 18 May 2020

Date of expiry: 18 May 2021



Certification Manager



0027

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Greater Manchester, M6 6AJ, England



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 Ltd documentation.

Sites

The quality system incorporates the following premise(s):

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

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.
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, 0194, 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.

INSPEC International Ltd, 56 Leslie Hough Way, Salford, Greater Manchester, M6 6AJ, England. Notified Body 0194

This certificate has been issued in accordance with our standard terms and conditions and subject to INSPEC Regulations and Conditions of Use. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with by the certified company.