CERTIFICATE LETTER

This is to certify that INSPEC International B.V., Notified Body 2849, has accepted transfer of type-examination (Module B) and/or approval decision (Module C2 or D) certification from INSPEC International Ltd, Notified Body 0194 in accordance with the transitional arrangements of the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and that the original Certificate(s) combined with this Certificate Letter evidences that INSPEC International B.V. deems them to be in compliance with 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 Transferred Certificate(s) listed on page 2.

Where a type-examination certificate has been transferred, this certificate, while valid, serves as authorisation to the manufacturer to reference INSPEC International B.V. within information supplied to the user, and their EU Declaration of Conformity.

Where an Approval Decision (Module C2 or D) has been transferred, this certificate, while valid, serves as authorisation to the manufacturer 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 certificate(s) for all production beyond the Date of current issue.

The Date of expiry of certification for the Type and / or Approval Decision is stated within the Transferred Certificate(s) listed on page 2. Where no expiry date is shown, the certificate shall expire on 21 April 2023 as per the transitional provisions of Article 47(2).

Date of initial certification: 11 December 2020
Date of current issue: 11 December 2020

2020/12/11

Certification Manager

Transferred Certificates

The following is a list of original certification documentation issued by INSPEC International Ltd, Notified Body 0194 which were transferred without revision to INSPEC International B.V., Notified Body 2849 and are confirmed as valid when combined with this certificate letter.

D-PPE20171075	PPE20161886

Certificate amendment record

Date	Description
11/12/2020	Initial Issue

General Conditions attached to the issue of this certificate:

1. The manufacturer / authorised representative shall undertake to fulfil the obligations arising out of the Personal Protective Equipment Regulation (EU) 2016/425, and with INSPEC's Regulations governing the Module as displayed on original Certificates.

2. Personal Protective Equipment Directive, 89/686/EEC, Article 10 certificates and Article 11.B approval decisions are valid under Personal Protective Equipment Regulation (EU) 2016/425, Article 47(2).

3. INSPEC International Ltd, Notified Body 0194, shall be absorbed into INSPEC International B.V. and closed – this is to be reflected on the EU NANDO website as "(ex-0194)" following the Body type "NB 2849". Therefore INSPEC International B.V. shall be available to verify certificates and references to the closed Notified Body 0194.

4. INSPEC International Ltd have requested that manufactures cease making reference to INSPEC International Ltd, Notified Body 0194 as soon as is practical, and to a date not later than 30 May 2021 for any production on or beyond 01 January 2021.

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 accompanied by the applicable Transferred Certificate(s), and without omissions or additions. Their use must be in accordance with INSPEC's terms of business.

Module B: Conditions attached to the issue of this certificate:

7. The manufacturer / authorised representative shall inform INSPEC of any planned changes to the product or technical file which may affect the validity of this certificate, before any such change is made.

8. Marking and instructions have been assessed in the English language only. It is the manufacturer's / authorised representative's responsibility to obtain and supply language versions acceptable to the country where the product is to be sold.

9. For category III product, the manufacturer must obtain and maintain an approval decision to Module C2 or Module D prior to placing product on the Union market.

Module C2: Conditions attached to the issue of this certificate

10. The manufacturer / authorised representative shall inform INSPEC of any planned changes to the product type which may affect the validity of this certificate.

11. For the certificate to remain valid a minimum of annual sampling to perform product checks must be conducted, as per Annex VII, 4.

12. 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 VII, 6.

Module D: Conditions attached to the issue of this certificate

13. 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.

14. 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.

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

16. 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.