

UKCA PRODUCTION CONFORMITY TO TYPE CERTIFICATE

This is to certify that INSPEC International Ltd, Approved Body 0194, has assessed the quality system of the manufacturer and deemed it to be in compliance with Module D of the Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended) and the Personal Protective Equipment (Enforcement) Regulations 2018.

Manufacturer: **Sundström Safety AB**
Västergatan 4
Lagan
SE-341 50
Sweden

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 approved 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: 04 June 2021
Date of current issue: 05 July 2024
Date of expiry: 06 July 2027


2024/07/05
Certificate Signatory

Product Types

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

Standard	Product type
EN136	Full facemask
EN140	Halfmasks for use with respiratory protective devices
EN143	Particle filters used in respiratory protective devices
EN403	Filtering respiratory protective devices with hood for self-rescue from fire
EN12083	Filters with breathing hoses (non-mask mounted filters)
EN12941	Respiratory protective devices. Powered filtering devices incorporating a helmet or a hood.
EN12942	Respiratory protective devices. Power assisted filtering devices incorporating full face masks, half -masks or quarter masks.
EN14387	Gas filters used in respiratory protective devices
EN14594	Continuous flow compressed air line breathing apparatus

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

Certificate amendment record

Date	Description
04/06/2021	Initial issue.
27/08/2021	Reissued following re-assessment.
05/07/2024	Reissued following re-assessment.

Conditions attached to the issue of this certificate

1. This certificate, in combination with a Module B Type-examination certificate, forms INSPEC's permission to the manufacturer to use the 'UKCA 0194' conformity mark for compliant products to be placed on the market in Great Britain (England, Wales and Scotland).
2. The manufacturer / authorised representative shall undertake to fulfil the obligations arising out of the quality system, and of the Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended), Module D, and with INSPEC's Regulations governing this Module.
3. The manufacturer / authorised representative shall inform INSPEC without delay of any planned changes to the quality system or manufacturer information which may affect the validity of this certificate, wherein INSPEC will proceed with evaluation of the proposals as per Annex VIII, 3.5.
4. For the certificate to remain valid audits and visits must be conducted, as per Annex VIII, 4.
5. The manufacturer may affix INSPEC's approved body identification number, 0194, to each PPE, and draw up a written declaration of conformity for each PPE model referencing this certificate and the Type-examination certificate(s) as per Annex VIII, 5.
6. This certificate remains the property of INSPEC and may be withdrawn if any of the conditions attached to its issue are not complied with.
7. 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.
8. The manufacturer shall not use its quality system certification in any manner as to bring INSPEC into disrepute, nor make any statements regarding the quality system certification that INSPEC considers misleading or unauthorised.
9. Upon suspension, withdrawal or termination of this certificate, the manufacturer must discontinue all advertising matter that references the quality system certification and take action as required by the Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended).