

UKNI PRODUCTION CONFORMITY TO TYPE CERTIFICATE

This is to certify that INSPEC International Ltd, NI Notified 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: **Ocenco, Incorporated / Erie Medical**
10225, 82nd Avenue
Pleasant Prairie
Wisconsin 53158
United States of America

The scope of the certification is for:

The manufacture of personal protective breathing apparatus for escape

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 NI 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: 28 March 2023
Date of current issue: 02 August 2024
Date of expiry: 03 August 2027


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
EN13794	Self-contained closed-circuit breathing apparatus for escape

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:	As per certificate holder address
Production location:	As per certificate holder address

Certificate amendment record

Date	Description
28/03/2024	Initial issue.
02/08/2024	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 'UKNI-CE 0194' conformity mark for compliant products to be placed on the market in Northern Ireland. The inclusion of 'CE' within the 'UKNI-CE 0194' mark does not permit products to be placed on the European Union market – separate certification must be sought.
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) and the Personal Protective Equipment (Enforcement) Regulations 2018, 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 NI Notified 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 to cease production of products.