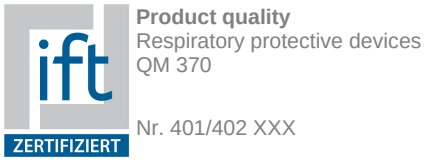
QM 370

Certification scheme for respiratory protective devices



Ve-ÜZ_-6469-en / 01.02.2021

ift Rosenheim GmbH
Theodor-Gietl-Str. 7-9
83026 Rosenheim
GERMANY

+49 8031 261-0
info@ift-rosenheim.de
www.ift-rosenheim.de

Notified Body 0757
PÜZ-Stelle BAY 18

Accredited Certification Body
Products + Services
EN ISO/IEC 17065

DAkkS Deutsche Akkreditierungsstelle D-ZE-11349-01-00

1 Basis

1.1 Purpose and scope

This certification scheme defines the requirements and procedure for the certification of respiratory protective devices, taking into account Regulation (EU) 2016/425 dated 09.03.2016 (Personal Protective Equipment Regulation; PPE Regulation).

Introduction and application of the specified provisions and tests ensure the sustainability of the characteristics of the respiratory protective devices demonstrated during testing.

1.2 Basis of testing and certification

This Certification Scheme lays down the requirements for certification and surveillance of respiratory protective devices. For certification and surveillance, ift-Q-Zert must be provided with the following evidence or the following basis apply:

- Proof of testing according to EN 149:2001+A1:2009 carried out by a testing body recognized by ift-Q-Zert,
- Technical documentation according to Annex III of Regulation (EU) 2016/425 dated 09.03.2016 (Regulation on personal protective equipment); including for the intended use or application of the respiratory protective devices,
- Contract with ift-Q-Zert on certification and surveillance of production of the products,
- Regulation (EU) 2016/425 dated 09.03.2016 (Regulation on personal protective equipment)
- The principles of EN ISO/IEC 17065.

1.3 Terms and definitions

1.3.1 Owner of test report

Organisation which commissions a testing body with identifying or testing specific or more than one product characteristic of a respirator and receives an evidence of performance/a report of the results obtained.

1.3.2 Manufacturer

Organisation that manufactures respiratory protective devices and/or places it on the European market under its name.

1.3.3 Product

Under the present certification scheme, product is defined as a respirator that is distributed on the basis of the specifications provided by the manufacturer for use according to EN 149:2001+A1:2009.

2 General procedure and contents of certification

The general procedure and the contents of the measures required for initial certification and renewal of certification are documented by ift-Q-Zert in the applicable "General requirements for certification, surveillance and inspection of products and services". The specifications defined in the following refer only to the certification of respiratory protective devices.

2.1 Certification procedure

- Conclusion of a certification and surveillance contract,
- Determination of the module (C2 or D) based on the PPE Regulation,
- Evaluation of the technical documentation according to Annex III of the PPE Regulation,
- EU-type examination incl. test report/evidence of performance,
- Certification procedure:
  - Based on a sample taken from the market (module C2),
  - Based on an initial inspection to the manufacturer's production site (Module D),
- EU-type examination certificate
- Sampling certificate (module C2) or surveillance certificate (module D).

3 EU-type examination certificate

3.1 Validity of the EU-type examination certificate

The EU-type examination certificate is issued for a period of 5 years.

As part of the recertification, the respirator must be retested after 5 years at a testing body recognized by ift-Q-Zert.

If all certification requirements (module C2 or module D) have been passed, the EU-type examination certificate will be renewed for a period of another 5 years.

The procedure for modifying or extending the certified scope as well as the suspension and revocation of certification is specified by ift-Q-Zert in the applicable ”General requirements for certification and surveillance/inspection of products and services”.

The EU-type examination certificate remains valid only as long as the provisions and requirements of this certification scheme as well as the product as such remain unchanged. Any changes to the product that have an effect on the characteristics verified by the test, shall be communicated to the certification body without being asked. ift-Q-Zert decides on necessary measures such as a product test.

In case of failure to comply with the provisions and measures specified by this certification scheme, the EU-type examination certificate as well as the right of affixing the mark to the respective products, will be withdrawn.

4 Procedure of conformity taking into account the PPE Regulation

As part of the certification process and to obtain conformity of the respirator, the manufacturer has the option, based on the PPE Regulation, to choose one of the certification modules described below.

4.1 Module C2 (Annex VII of the PPE Regulation)

4.1.1 EU-type examination

Within the EU-type examination for a respirator, evidences according to EN 149:2001+A1:2009, issued by a notified testing body recognized by ift-Q-Zert, must be submitted. Furthermore, the manufacturer has to provide the technical documentation according to Annex III of Regulation (EU) 2016/425 dated 09.03.2016 (Regulation on personal protective equipment).

For evaluation of the documents, ift-Q-Zert may rely on further documentation provided by an ift recognised testing body.

4.1.2 Sampling

In order to continue certification, representative samples of products on the market are taken at least once a year and subjected to a complete test according to EN 149:2001+A1:2009 at ift Rosenheim. As a result of the sampling, the manufacturer receives a sampling report.

In the event of a negative result of the test, a new sampling is made with an increased number of samples.

ift-Q-Zert reserves the right to conduct an additional inspection of the quality assurance system in the manufacturing plant of the respiratory protective devices in the course of a negative random sampling.

4.1.2.1 Sampling certificate

In addition to the EU-type examination certificate and the sampling report, the manufacturer receives a sampling certificate. This certifies that he or his product maintains continuous quality assurance in the certification interval according to module C2.

4.1.2.2 Marking

The manufacturer of the respiratory protective devices shall ensure that the products are marked according to EN 149:2001+A1:2009 and the "ift-certified" mark (QM 204).

In addition to the prescribed marking, marking in digital form is also permissible.

The right of affixing the quality mark expires automatically by terminating the certification and surveillance contract, or in the event of non-compliance with the criteria laid down by this certification scheme.

4.2 Module D (Annex VIII of PPE Regulation)

4.2.1 EU-type examination

Within the EU-type examination for a respirator, evidences according to EN 149:2001+A1:2009, issued by a notified testing body recognized by ift-Q-Zert, must be submitted. Furthermore, the manufacturer has to provide the technical documentation according to Annex III of Regulation (EU) 2016/425 dated 09.03.2016 (Regulation on personal protective equipment).

For evaluation of the documents, ift-Q-Zert may rely on further documentation provided by an ift recognised testing body.

4.2.2 Initial audit

The objective of the initial inspection is to check the personnel and manufacturing conditions for manufacturing respiratory protective devices on the basis of this certification scheme. Initial inspection includes the evaluation of the existing quality assurance system.

4.2.2.1 Surveillance certificate

In addition to the EU-type examination certificate, the manufacturer receives a surveillance certificate. This certifies that he or his product maintains continuous quality assurance in the certification interval according to module D.

4.2.2.2 Marking

The manufacturer of the respiratory protective devices shall ensure that the products are marked according to EN 149:2001+A1:2009 and the "ift-certified" mark (QM 204).

In addition to the prescribed marking, marking in digital form is also permissible.

The right of affixing the quality mark expires automatically by terminating the certification and surveillance contract, or in the event of non-compliance with the criteria laid down by this certification scheme.

4.2.3 Third party control

4.2.3.1 General

Contents, rights and duties are described by ift-Q-Zert in the applicable relevant documents "General requirements for certification, surveillance and inspection of products and services".

4.2.3.2 Intervals and contents

Surveillance by means of a visit to the monitored site (production facility or facilities) is carried out once a year and includes:

- Verification of the quality assurance system,
- Checking of staff qualifications and manufacturing conditions,
- Inspection for any obvious defects of the measuring instruments used as well as verification of availability of valid certificates referring to calibration and service/maintenance of the measuring instruments. Inspections of measuring instruments must be documented.

4.2.3.3 Surveillance report

An audit report is prepared on the findings of the surveillance. If one or more measured values are beyond the specified limit values, the cause of the non-conformity must be identified and eliminated at short term. After elimination of defects, the certification body decides whether additional quality assurance measures are required (e.g. a special audit/inspection).

4.2.3.4 Remedy of defects/non-conformities - Special audit

Special audits may become necessary as a consequence of:

- negative evaluation of surveillance or
- complaints received from the market about the certified products

4.2.3.5 Deadlines to remedy defects/non-conformities

As a rule, the deadline provided for discharge of nonconformities detected during the regular audit should not exceed three months. As a rule, the deadline provided for discharge of defects detected during the special audit is set at one month.

4.2.4 Quality assurance system

4.2.4.1 General

The manufacturer of respiratory protective devices undertakes to establish a system of quality assurance to assure consistent characteristics of respiratory protective devices. The manufacturer shall name at least one employee responsible for certification who has the authority, knowledge and experience in the production process of respiratory protective devices. This employee is responsible for due implementation of quality assurance. If unallowed non-conformities are detected during quality assurance, the person responsible for quality assurance shall immediately initiate measures to eliminate such non-conformities or defects.

Quality assurance includes the following mandatory inspections/tests:

- Material control/control of incoming goods
- Production control,
- Inspection of marking,
- Internal product testing.

Suitable equipment and devices shall be provided for performing factory production control. For the number of samples, the minimum AQL value is 1.5 in the special sample S2 of ISO 2859-1:1999 + Corr.1:2001 + AMD 1:2011.

4.2.4.2 Material control/control of incoming goods

The following shall be observed for material control/control of incoming goods:

- Control of incoming goods (including fabrics, tile, chemicals, tapes, rubber materials, etc.),

Manufacturer's certificate of conformity based on EN 10204:2004, Clause 2.2 are permitted.

4.2.4.3 Production control

Production control to assure consistent characteristics of respiratory protective devices shall be carried out and documented adequately, at least in accordance with ISO 2859-1:1999 + Corr.1:2001 + AMD 1:2011, S2, AQL 1.5.

4.2.4.4 Internal product testing

As part of his quality assurance control, the manufacturer shall provide evidence of testing according to EN 149:2001+A1:2009 at least once a year for each design/product variant.