

EN 143 AND RELATED STANDARDS

APPLICATION NOTE AFT-003

Introduction

Procedures for testing and certifying air-purifying and particulate respirators in Europe are governed by European standards EN 143:2000 (Respiratory protective devices -Particle filters - Requirements, testing, marking) and a number of related standards. All of these related standards refer to EN 143 for the certification test method. The certification process and the requirements for quality control testing are described in the EU PPE (European Union – Personal Protective Equipment) guidelines and are applicable to all personal protection equipment. All respirator filters fall under categories II or III.

As such, all respirators require technical documentation and EC type-examination testing (at an accredited lab). Examples of labs are BGIA in Germany and HSL in the UK.

Category III filter products require “CE nnnn” type certificate (for example CE EN 143). That category also requires some type of quality system to assure the quality of the respirators being manufactured.

These associated standards apply to various classes of respirators. Examples are:

- Filtering face-pieces (disposable masks) (EN 149) (Respiratory protective devices - Filtering half masks for protection against particles - Requirements, testing, marking)
- Re-usable half masks (EN 405 or EN 140, filters: EN 141, EN 143, EN 371, EN 372)
- Re-usable full face masks (EN 136)
- SCBA self contained breathing apparatus (EN 137 or EN 145)

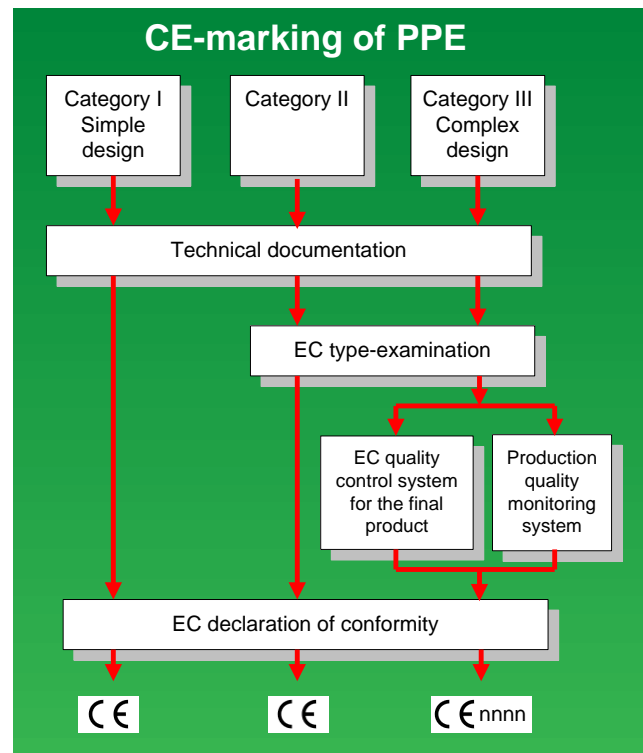


Figure 1 European PPE Guidelines



Below is the Filter Classification system for these standards.

Table 1: Filter Classification under EN 143 and Related Standards

Filter Class	Maximum breathing resistance (mbar*)		Maximum filter penetration of test aerosol (%)	
	at 30 l/min	at 95 l/min	Sodium chloride test at 95 l/min	Paraffin oil test at 95 l/min
P1	0,6	2,1	20	20
P2	0,7	2,4	6	6
P3	1,2	4,2	0,05	0,05
* 1 bar = 10 ⁵ N/m ² = 100 kPa				

Filtering face-pieces are classified according to EN 149 as FFP1, FFP2 and FFP3 with protection factors of 4, 10 and 30, respectively.

TEST REQUIREMENTS FOR EN STANDARDS

Certification Tests

The EN certification tests require both sodium chloride (NaCl) and paraffin oil. Clean filters are tested for breathing resistance at both 30 liters per minute (l/min) and at 95 l/min. The initial filter penetration is also measured on clean filters. Several filters are tested with sodium chloride and several are tested with paraffin oil. Next, these filters are loaded with dolomite dust to either a maximum breathing resistance

(4, 5 or 7 mbar for P1, P2 or P3, respectively) or until the product of dolomite dust concentration ($400 \pm 100 \text{ mg/m}^3$) times test time (h) equals $263 \text{ mg} \times \text{h/m}^3$ (whichever comes first). The penetrations of the filters are then measured a second time with the aerosol that they were originally tested with and compared to the Filter Classification requirements. Both the initial breathing resistance and the penetration value (before as well as after loading) must be met to qualify for a specific filter class.

When performing the sodium chloride test, the maximum penetration for the filters tested must be less than or equal to the filter penetration criterion for the filter class for which approval is sought. For example, when testing with NaCl, a P2 filter must demonstrate filter penetrations less than or equal to 6%.

Similarly, when doing the paraffin oil test, the maximum penetration for the filters tested must be less than or equal to the filter penetration criterion for the filter class for which approval is sought. For example, when testing with paraffin oil, a P3 filter must demonstrate filter penetrations less than or equal to 0,05%.

The TSI model 8130-EN (-EN version) has been determined to give equivalent test results to the equipment that is used by accredited test labs in Europe for both paraffin oil and sodium chloride aerosols. See "BGIA Test Report" for more details. As such the model 8130 for both can perform certification-equivalent tests with both aerosol types and is useful for developing respirators that will satisfy the EN 143 test requirements.

EN certification approval process requires that multiple filters will be tested at an accredited test lab. The maximum penetration of each of the filters will be determined and recorded and should be less than or equal to the filter penetration criterion listed for each level in order to be approved.

Quality Control Tests

As a part of each application for European type III respirator approval, a quality control plan must be submitted, and approved. The quality control plan can take the form of either a quality control system for the final product or a quality monitoring (QM) system. Production QM testing can be done either by the manufacturer (regular audits are necessary) or statistically by an accredited lab.

This quality control plan shall include a procedure for the selection of a sample of respirators and the components for testing. Certification types of testing, like those required for approval, may be a part of a quality control plan, but shorter, non-destructive quality control tests are the main component of most quality control plans. The TSI model 8127-EN (paraffin oil) and the model 8130-EN (paraffin oil and sodium chloride) can perform instantaneous penetration tests, suitable for quality control testing, in as little as 12 seconds. These tests can be done with aerosol test conditions (aerosol size distribution to give equivalent penetration results) and mass concentrations that are used in the certification tests.

TSI 8127-EN and 8130-EN used for EN 143 Compliance

The data in Table 2 describes the test requirements that are described in the EN 143. The table also provides in detail the apparatus and parameter set forth in the standard and the applicability of TSI products (Model 8127-EN, 8130-EN, and 3936) in fulfilling those requirements.

Table 2: Test Setting for EN 143 and related standards

Test/Parameters	Settings (for Equivalent Test Results)	8127-1-EN	8130-1-EN
Test Classification			
Tests	<ul style="list-style-type: none"> Aerosol concentration: $20 \pm 5 \text{ mg/m}^3$ Paraffin Oil Aerosol concentration: $8 \pm 4 \text{ mg/m}^3$ NaCl 20%, 6%, and 0,05% penetration 	✓	✓
Quality control tests	Manufacturer defined filter efficiency checks	✓	✓
Test Parameter			
Paraffin oil aerosol*	<ul style="list-style-type: none"> Count Median Diameter (CMD): $0,16 \mu\text{m}$ Geometric Standard Deviation (σ_g) ~ 2 	✓	✓
NaCl aerosol*	<ul style="list-style-type: none"> Count Median Diameter (CMD): $0,06 \mu\text{m}$ Geometric Standard Deviation (σ_g) $\sim 1,9$ 	Not Applicable	✓
Aerosol detection	Light Scattering Photometer**	✓	✓
Challenge flow rate	95 l/min ($\pm 5\%$) ***	✓	✓
Aerosol temperature	Ambient	✓	✓

* Particle size distribution can be measured using TSI 3936 Scanning Mobility Particle Sizer™ Spectrometer

** Equivalent method (compared to flame photometer for sodium chloride detection)

*** For a single filter respirator (flow rate decreases with multiple respirators)

As evident from the table, both 8127-EN and 8130-EN filter testers meet the rigorous requirements of EN 143 and related standards. The TSI models 8127 and 8130 have been standard equipment for more than a decade in meeting respirator standard requirements in many parts of the world. With the addition EN 143 equivalency, the new model 8127-EN and 8130-EN (or adding –EN version generator to 8127 and 8130 testers) can now meet the requirements of European standards.

With model 8130, when equipped with both the standard and –EN style generators, can meet the requirements of respirator standard around the world. Now one filter tester can be used where multiple testers were previously needed.

For more information about applications of TSI's automated filter testers go to <http://filtertest.tsi.com/>.



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