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STANDARD

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JIS K 3801 : 2000

(JBA/JSA)

**Test method of HEPA filters
for microbiological use**

ICS 11.080.10

Descriptors : air filters, biological hazards, leak tests, penetration tests, aerosols,
particle size measurement, performance testing, dust control, sterilization
(hygiene)

Reference number : JIS K 3801 : 2000 (E)

Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of International Trade and Industry through deliberations at the Japanese Industrial Standards Committee based on the draft proposal for the revision of Japanese Industrial Standard offered by Japan Bioindustry Association (JBA)/Japanese Standards Association (JSA) in accordance with the provision of Clause 1, Article 12 of the Industrial Standardization Law.
Consequently **JIS K 3801 : 1989** is replaced with this Standard.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Test method of HEPA filters for microbiological use

1 Scope This Japanese Industrial Standard specifies the method for testing microbiological filtration performance of HEPA filters (high efficiency particulate air filters) based on leakage rate of filter using test particles.

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. The most recent editions of the standards indicated below shall be applied.

JIS B 9921 *Light scattering automatic particle counter*

JIS B 9927 *Cleanroom—Air filters—Test methods*

JIS K 3600 *Biotechnology—Vocabulary*

JIS Z 8122 *Contamination control—Terminology*

JIS Z 8901 *Test powders and test particles*

3 Definitions For the purposes of this Standard, definitions given in **JIS K 3600** and **JIS Z 8122** shall apply.

4 Summary of testing method The summary of the testing method is as follows; Supply particles specified in **JIS Z 8901** not less than a fixed concentration to the upstream side of a testing HEPA filter unit, scan the downstream side thereof by using a light scattering automatic particle counter, and examine the microbiological filtration performance by measuring the number of leaked particles of not less than 0.3 μm in particle size and its ratio.

5 Apparatus used for test

5.1 Light scattering automatic particle counter A light scattering automatic particle counter has a recording function for particle concentration in air and particle size classification specified in **JIS B 9921**.

5.2 Scanning leak testing apparatus The structure of each part of a scanning leak testing apparatus shall be as follows. An example thereof is given in Fig. 1.

- a) **Testing aerosol generator** Class 1 (DOP) of test particles 2 specified in **JIS Z 8901** or aerosols equivalent thereto shall be able to be continuously generated in a stabilized state. The aerosol shall be supplied at an inlet of a blower, or otherwise shall be supplied to other places where mixing is performed so that particle concentration on a filter upstream side becomes uniform.
- b) **Upstream duct** An upstream duct shall be so constructed as to be able to obtain an uniform test particle concentration and air speed distribution.
- c) **Upstream side particle concentration measuring hole** A measuring hole shall be located where test particles are uniformly mixed.