

# ISO 27427:2010-03 (E)

## Anaesthetic and respiratory equipment - Nebulizing systems and components

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1 *Scope .....		1
2 Normative references .....		1
3 Terms and definitions .....		3
4 General requirements and requirements for test .....		4
4.1 Risk management .....		4
4.2 *Test methods and alternatives .....		4
4.3 Electrical safety .....		5
4.4 Mechanical safety .....		5
4.5 Pneumatic safety .....		5
4.6 Protection against inadvertent adjustments .....		5
4.7 Protection against infection .....		5
4.8 Usability .....		5
5 Marking and instructions for use .....		6
5.1 Marking .....		6
5.2 Symbols .....		7
5.3 Instructions for use .....		7
6 Construction requirements .....		9
6.1 Materials .....		9
6.2 Connectors .....		10
6.3 Rotary controls .....		13
7 Cleaning, sterilization and disinfection .....		13
8 Biocompatibility .....		13
Annex A (informative) Rationale .....		14
Annex B (normative) Diameters of respirable fraction particles .....		16
Annex C (normative) Test methods for aerosol output and aerosol output rate .....		17
Annex D (normative) Test methods for particle sizing .....		21
Annex E (informative) Test apparatus for leak test .....		27
Annex F (informative) Hazard identification for risk assessment .....		28
Annex G (informative) Taxonomy of general purpose nebulizers .....		35
Annex H (informative) Environmental aspects .....		37
Annex AA (informative) Conformance to essential principles .....		38
Bibliography .....		42