

# DIN EN ISO 18472:2006-10 (E)

## Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2006)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		2
Introduction .....		4
1	Scope .....	5
2	Normative references .....	5
3	Terms and definitions .....	6
4	Performance requirements for resistometers .....	8
4.1	Intended use .....	8
4.2	Measurement and control capabilities .....	8
4.3	Test methods .....	8
4.4	Leak test .....	8
4.5	Steam resistometer performance requirements .....	8
4.6	Ethylene oxide resistometer performance requirements .....	11
4.7	Dry heat (heated air) resistometer performance requirements .....	13
4.8	Vaporized hydrogen peroxide process resistometer performance requirements .....	15
5	Recording systems .....	16
5.1	Measurement systems .....	16
5.2	Calibration .....	16
6	Documentation .....	16
6.1	General .....	16
6.2	Minimum information .....	17
Annex A (informative) Additional performance characterization -- Steam .....		18
Annex B (informative) Additional performance characterization -- Ethylene oxide .....		21
Annex C (informative) Additional performance characterization - Dry heat .....		24
Annex D (informative) Resistometer documentation and derivations .....		26
Bibliography .....		32