

# DIN EN ISO 18472:2018-11 (E)

## Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2018)

---

<b>Contents</b>	<b>Page</b>
European foreword .....	3
Foreword .....	4
Introduction .....	5
<b>1 Scope</b> .....	<b>6</b>
<b>2 Normative references</b> .....	<b>6</b>
<b>3 Terms and definitions</b> .....	<b>7</b>
<b>4 Performance requirements for resistometers</b> .....	<b>9</b>
4.1 Intended use .....	9
4.2 Test methods .....	9
4.3 Air leakage test .....	9
4.4 Steam resistometer performance requirements .....	10
4.4.1 Measurement accuracy .....	10
4.4.2 Data .....	10
4.4.3 Process control .....	10
4.4.4 General steam resistometer requirements .....	11
4.4.5 Air leakage test .....	12
4.4.6 Operation of steam resistometer .....	12
4.5 Ethylene oxide gas resistometer performance requirements .....	12
4.5.1 Measurement accuracy .....	12
4.5.2 Data .....	13
4.5.3 Process control .....	13
4.5.4 General ethylene oxide gas resistometer requirements .....	14
4.5.5 Air leakage test .....	15
4.5.6 Operation of ethylene oxide gas resistometer .....	15
4.6 Dry heat (heated air) resistometer performance requirements .....	15
4.6.1 Measurement accuracy .....	15
4.6.2 Data .....	16
4.6.3 Process control .....	16
4.6.4 General dry heat (heated air) resistometer requirements .....	17
4.6.5 Operation of dry heat (heated air) resistometer .....	17
4.7 Vaporized hydrogen peroxide resistometer performance requirements .....	18
4.7.1 Measurement accuracy .....	18
4.7.2 Recording interval .....	18
4.7.3 Process control .....	18
4.7.4 General vaporized hydrogen peroxide resistometer requirements .....	19
4.7.5 Air leakage test .....	20
4.7.6 Operation of vaporized hydrogen peroxide resistometer .....	20
<b>5 Calibration</b> .....	<b>20</b>
<b>Annex A (informative) Additional performance characterization — Steam</b> .....	<b>21</b>
<b>Annex B (informative) Additional performance characterization — Ethylene oxide gas</b> .....	<b>24</b>
<b>Annex C (informative) Additional performance characterization — Dry heat</b> .....	<b>27</b>
<b>Annex D (informative) Resistometer documentation and derivations</b> .....	<b>29</b>
<b>Bibliography</b> .....	<b>35</b>