

# DIN EN 16442:2015-05 (E)

## Controlled environment storage cabinet for processed thermolabile endoscopes

---

<b>Contents</b>		<b>Page</b>
Foreword .....		4
Introduction .....		5
1	Scope .....	6
2	Normative references .....	6
3	Terms and definitions .....	6
4	Performance requirements .....	7
4.1	General .....	7
4.2	Storage .....	8
4.3	Drying .....	8
4.4	Endoscope storage cabinet connectors (ESC connectors) .....	9
5	Mechanical and procedure requirements .....	9
5.1	Materials - design, manufacture and assembly .....	9
5.2	Air quality .....	10
5.3	Contamination of the storage cabinet chamber surfaces .....	11
5.4	Drying process control .....	11
5.5	Endoscope channel aeration system .....	12
5.6	Automatic temperature control .....	13
5.7	Fault indication/monitoring .....	13
5.8	Cycle indicators .....	14
5.9	Instruments and control devices .....	14
5.10	Temperature indicators .....	15
5.11	Relative humidity indicator .....	15
5.12	Pressure indicators .....	15
5.13	Traceability .....	16
5.14	Double-ended storage cabinets .....	16
6	Testing for conformity .....	17
6.1	General .....	17
6.2	Air changes .....	17
6.3	Overpressure .....	17
6.4	Drying .....	18
6.5	Contamination of the inside surfaces of the storage cabinet .....	19
6.6	Air quality .....	19
6.7	Channel aeration test .....	21
6.8	Thermometric testing 1 - chamber and load temperature testing .....	21
6.9	Thermometric test 2- chamber and load temperature testing .....	22
6.10	Readability .....	22
6.11	Tests for air filtration .....	22
7	Documentation .....	22
8	Information to be supplied with the storage cabinet .....	22
8.1	General .....	22
8.2	Information to be supplied before delivery .....	23
8.3	Marking and labelling .....	25
8.4	Packaging .....	25

<b>9</b>	<b>Information to be requested from the purchaser by the manufacturer .....</b>	<b>25</b>
	<b>Annex A (informative) Summary of test programmes .....</b>	<b>26</b>
	<b>Annex B (informative) Cross-contamination between endoscopes .....</b>	<b>28</b>
	<b>Annex C (normative) Methods for evaluation of airborne microbial contamination in the storage cabinet .....</b>	<b>31</b>
	<b>Annex D (informative) Procedure for parametric performance qualification .....</b>	<b>32</b>
	<b>Annex E (normative) Internal residual contamination of endoscopes after storage .....</b>	<b>38</b>
	<b>Annex F (normative) Establishing endoscope type test groups .....</b>	<b>46</b>
	<b>Annex G (normative) Establishing endoscope product families .....</b>	<b>55</b>
	<b>Bibliography .....</b>	<b>59</b>