

# DIN EN 1422:2014-08 (E)

## Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

---

<b>Contents</b>		<b>Page</b>
Foreword .....		4
Introduction .....		5
1	Scope .....	6
2	Normative references .....	6
3	Terms and definitions .....	7
4	Technical requirements .....	12
4.1	General .....	12
4.1.1	Risk control and usability .....	12
4.1.2	Materials .....	13
4.2	Sterilizer chamber .....	13
4.2.1	Chamber size .....	13
4.2.2	Doors, closures and interlocks of the sterilizer chamber .....	13
4.2.3	Test connections .....	14
4.3	Design and construction .....	15
4.3.1	General .....	15
4.3.2	EO vaporizers .....	15
4.3.3	Pipework and fittings .....	15
4.3.4	Evacuation system .....	15
4.3.5	Control valves .....	16
4.3.6	Thermal insulation .....	16
4.3.7	Electrical and mechanical safety .....	16
4.3.8	Air or inert gas filter .....	16
4.3.9	Emission control .....	16
4.3.10	Framework and panelling .....	17
4.3.11	Loading equipment .....	17
4.3.12	Transport .....	17
4.4	Indicating, measuring, and recording instruments .....	17
4.4.1	General .....	17
4.4.2	Temperature sensor .....	18
4.4.3	Temperature indicating instruments .....	18
4.4.4	Pressure sensors .....	19
4.4.5	Timers and time indicating instruments .....	19
4.4.6	Sterilizing cycle counter .....	19
4.4.7	Relative humidity (RH) sensors .....	19
4.4.8	Ethylene Oxide (EO) concentration-measurement .....	19
4.4.9	Recording instruments .....	20
4.4.10	Indicating instruments .....	21
5	Process control .....	22
5.1	General .....	22
5.2	Software verification and validation .....	23
5.3	Sterilization cycle and automatic control .....	23
5.3.1	Automatic control .....	23
5.3.2	Sterilization cycle .....	24
5.4	Override of automatic control .....	27
5.5	Fault .....	27

<b>6</b>	<b>Performance requirements</b> .....	<b>28</b>
6.1	Sterilizing performance .....	28
6.1.1	Loading configuration .....	28
6.1.2	Physical parameters .....	28
6.1.3	Microbiological efficacy .....	28
6.2	EO removal (flushing) .....	29
6.3	Aeration .....	29
<b>7</b>	<b>Sound power</b> .....	<b>29</b>
<b>8</b>	<b>Packaging, marking and labelling</b> .....	<b>29</b>
<b>9</b>	<b>Information to be supplied by the manufacturer</b> .....	<b>30</b>
<b>10</b>	<b>Service and local environment</b> .....	<b>32</b>
10.1	General .....	32
10.2	Electricity .....	33
10.3	Sterilant .....	33
10.4	Circulation systems .....	33
10.5	Steam .....	33
10.6	Water .....	34
10.7	Air and inert gasses .....	34
10.8	Drainage and discharges .....	34
10.9	Ventilation and environment .....	34
10.10	Lighting .....	34
<b>Annex A (normative) Test instrumentation</b> .....		<b>35</b>
<b>Annex B (normative) Leak test cycle</b> .....		<b>36</b>
<b>Annex C (normative) Sterilizer chamber profile testing</b> .....		<b>37</b>
C.1	Sterilizer chamber internal surfaces .....	37
C.2	Empty sterilizer chamber .....	37
<b>Annex D (normative) Microbiological test for EO sterilizers</b> .....		<b>38</b>
D.1	General .....	38
D.2	Test equipment .....	38
D.3	Procedure .....	39
D.4	Interpretation of results .....	40
<b>Annex E (informative) Environmental aspects</b> .....		<b>41</b>
E.1	Environmental aspects regarding the life cycle of EO sterilizers .....	41
E.2	EO (brief description) .....	41
E.3	Environmental impact .....	41
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices</b> .....		<b>44</b>
<b>Bibliography</b> .....		<b>48</b>