

# DIN EN ISO 16571:2024-09 (E)

## Systems for evacuation of plume generated by medical devices (ISO 16571:2024)

<b>Contents</b>		<b>Page</b>
European foreword.....		3
Foreword.....		4
Introduction.....		5
<b>1</b>	<b>Scope</b> .....	<b>6</b>
<b>2</b>	<b>Normative references</b> .....	<b>7</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>7</b>
<b>4</b>	<b>General requirements</b> .....	<b>12</b>
4.1	Components.....	12
4.2	Systems.....	12
4.3	Capture device.....	13
4.4	Transfer tubing.....	14
4.5	Filtration subsystem.....	14
4.6	Control subsystem.....	14
4.7	Flow-generator.....	14
4.8	Exhaust subsystem.....	15
4.9	Colour coding.....	15
<b>5</b>	<b>Portable and mobile system requirements</b> .....	<b>15</b>
5.1	General requirements.....	15
5.2	Acoustic noise test.....	15
5.3	Ingress protection.....	17
<b>6</b>	<b>Stationary and pipeline system requirements</b> .....	<b>17</b>
6.1	Stationary plume evacuation systems.....	17
6.2	Design.....	17
6.3	Flow-generators.....	18
6.4	Exhausts.....	18
6.5	Flow-generator controls.....	18
6.6	Pipeline.....	19
6.7	Terminal units.....	19
6.8	Commissioning and testing.....	19
<b>7</b>	<b>Endoscopic and laparoscopic system requirements</b> .....	<b>20</b>
7.1	Active PESs.....	20
7.2	Passive PESs.....	20
<b>Annex A (informative) Rationale</b> .....		<b>22</b>
<b>Annex B (informative) Plume evacuation system implementation</b> .....		<b>25</b>
<b>Annex C (normative) Plume removal efficiency test method</b> .....		<b>28</b>
<b>Annex D (normative) Colour coding</b> .....		<b>34</b>
<b>Annex E (normative) Information to be supplied to the healthcare facility</b> .....		<b>37</b>
<b>Annex F (informative) Acoustic testing muffler design</b> .....		<b>40</b>
<b>Bibliography</b> .....		<b>42</b>