

# DIN EN ISO 7396-3:2026-01 (E)

## Medical gas pipeline systems - Part 3: Proportioning units for the production of synthetic medical air (ISO 7396-3:2025)

---

<b>Contents</b>		<b>Page</b>
<b>Foreword</b>		v
<b>Introduction</b>		vi
<b>1 Scope</b>		<b>1</b>
<b>2 Normative references</b>		<b>1</b>
<b>3 Terms and definitions</b>		<b>2</b>
<b>4 Nomenclature</b>		<b>5</b>
4.1	General	5
4.2	Components of a proportioning unit	5
<b>5 General requirements</b>		<b>6</b>
5.1	Safety	6
5.2	Usability	6
5.3	Materials	6
<b>6 Design requirements</b>		<b>7</b>
6.1	Environmental conditions	7
6.2	Specification for synthetic medical air	7
6.3	Management of the conformity of supply	7
6.4	Sample port	8
6.5	Outlet connector	8
6.6	Inlet connectors: Pressure-equalizing system	8
6.6.1	Inlet connectors	8
6.6.2	Pressure-equalizing system	8
6.7	Requirements for outlet pressure	8
6.8	Indication of the functional parameters	9
6.9	Monitoring and alarm systems	9
6.10	Record capability	9
6.11	Leakage	10
6.12	Manual shut-off valves	10
6.13	Automatic shut-off valves	10
6.14	Non-return valves	10
6.15	Pressure-relief valves	10
6.16	Mechanical strength	10
6.17	Filtration	11
6.18	Electromagnetic compatibility	11
6.19	Electrical safety	11
6.20	Oxygen analysers	11
6.21	Software	12
6.22	Enclosure	12
<b>7 Constructional requirements</b>		<b>12</b>
7.1	Cleanliness	12
7.2	Lubricants	12
<b>8 Type test methods</b>		<b>12</b>
8.1	General	12
8.2	Test method for compliance of synthetic medical air to specification	12
8.3	Test method for leakage	12
8.4	Test method for alarms	13

8.5	Test method for mechanical strength.....	13
8.6	Test method for performance.....	13
8.7	Electromagnetic compatibility test.....	13
8.8	Electrical safety test.....	13
8.9	Test method for automatic shut-off valve.....	13
8.10	Test for enclosure.....	13
<b>9</b>	<b>Marking and packaging.....</b>	<b>14</b>
9.1	Marking.....	14
9.2	Packaging.....	14
<b>10</b>	<b>Information supplied by the manufacturer.....</b>	<b>14</b>
10.1	General.....	14
10.2	Information for installation.....	14
10.3	Instructions for use.....	15
10.4	Information for maintenance.....	15
<b>Annex A (informative) Typical example of a proportioning unit with terminology.....</b>		<b>16</b>
<b>Annex B (informative) Typical forms for documenting compliance of the proportioning unit with the requirements of this document.....</b>		<b>17</b>
<b>Annex C (informative) Rationale.....</b>		<b>24</b>
<b>Annex D (informative) List of potential hazards.....</b>		<b>25</b>
<b>Bibliography.....</b>		<b>26</b>