

# ISO 18835:2015-04 (E)

## Inhalational anaesthesia systems - Draw-over anaesthetic systems

---

| Contents                                                            | Page |
|---------------------------------------------------------------------|------|
| Foreword .....                                                      | iv   |
| Introduction .....                                                  | v    |
| 1      * Scope .....                                                | 1    |
| 2      Normative references .....                                   | 1    |
| 3      Terms and definitions .....                                  | 1    |
| 4      General requirements .....                                   | 2    |
| 4.1    Risk management .....                                        | 2    |
| 4.2    Construction .....                                           | 3    |
| 4.3    Performance .....                                            | 4    |
| 4.4    * Components for use with flammable anaesthetic agents ..... | 4    |
| 4.5    Materials .....                                              | 4    |
| 4.6    Mechanical hazards .....                                     | 4    |
| 4.7    Particulate matter .....                                     | 4    |
| 4.8    Environmental requirements .....                             | 4    |
| 5      Draw-over vaporizer .....                                    | 5    |
| 5.1    Construction .....                                           | 5    |
| 5.2    Performance .....                                            | 5    |
| 5.3    * Ports and connectors .....                                 | 6    |
| 6      Breathing system .....                                       | 6    |
| 6.1    Construction .....                                           | 6    |
| 6.2    Performance .....                                            | 7    |
| 6.3    Ports and connectors .....                                   | 7    |
| 7      Reservoir .....                                              | 7    |
| 7.1    Construction .....                                           | 7    |
| 7.2    Performance .....                                            | 7    |
| 7.3    Ports and connectors .....                                   | 8    |
| 8      Bellows-type manual ventilator .....                         | 8    |
| 8.1    * Construction .....                                         | 8    |
| 8.2    Performance .....                                            | 8    |
| 8.3    Ports and connectors .....                                   | 9    |
| 9      Marking of operator-assembled components .....               | 9    |
| 9.1    General .....                                                | 9    |
| 9.2    Marking of the draw-over vaporizer .....                     | 9    |
| 9.3    Marking of breathing-system attachments .....                | 10   |
| 9.4    Marking of reservoir .....                                   | 10   |
| 9.5    Marking of bellows-type manual ventilator .....              | 10   |
| 9.6    Marking of packages .....                                    | 11   |
| 10     Information supplied by the manufacturer .....               | 11   |
| Annex A (informative) Rationale .....                               | 13   |

|                                                                          |           |
|--------------------------------------------------------------------------|-----------|
| <b>Annex B (normative) Test methods .....</b>                            | <b>15</b> |
| <b>Annex C (informative) Environmental aspects .....</b>                 | <b>17</b> |
| <b>Annex D (informative) Reference to the essential principles .....</b> | <b>18</b> |
| <b>Bibliography .....</b>                                                | <b>22</b> |