PRODUCT MANUAL FOR ANAESTHETIC MACHINES FOR USE WITH HUMANS ACCORDING TO IS 11378:2002 / ISO 5358:1992

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	**Product**	**:**	IS 11378:2002 / ISO 5358:1992
	Title	**:**	Anaesthetic Machines for use with Humans
	No. of amendments	**:**	Nil
2.	**Sampling Guidelines**		
a)	**Raw material**	**:**	The various components used shall be such that they meet all requirements of the design and construction of various clauses of IS 11378.
b)	**Grouping Guidelines**	**:**	Please refer **Annex - A**
c)	**Sample Size**	**:**	One Complete Machine.
3.	**List of Test Equipment**	**:**	Please refer **Annex - B**
4.	**Scheme of Inspection and Testing**	**:**	Please refer **Annex - C**
5.	**Possible tests in a day**	**:**	As the licence is operated on Factory Testing basis, complete testing of a sample shall be done in factory.
6.	**Scope of the Licence:**		
	Licence is granted to use Standard Mark as per IS 11378:2002 with the following scope:		
	Name of the product	Anaesthetic machines for use with humans	
	Any other aspect required as per the Standard	With / without built-in-monitor and / or oxygen analyzer and/ or gas mixer	

BUREAU OF INDIAN STANDARDS
Manak Bhawan, 9, Bahadur Shah Zafar Marg,
New Delhi – 110002

ANNEX A

Grouping Guidelines

1. Anaesthetic Machines for use with Humans as per IS 11378:2002 are of the following varieties:

   a) With / without Built-in Monitor
   b) With / without Oxygen Analyzer
   c) With / without Gas Mixer

2. For considering GoL/CSoL, one complete machine of each variety as per Sl no. 1 (a, b & c) above shall be tested for all requirements.

3. However, the following relaxation may be given:

   a) If Anaesthetic Machine with Built-in Monitor is tested then Anaesthetic Machine without Built-in Monitor may also be covered.

   b) If Anaesthetic Machine with Oxygen Analyzer is tested then Anaesthetic Machine without Oxygen Analyzer may also be covered.

   c) If Anaesthetic Machine with Gas Mixer is tested then Anaesthetic Machine without Gas Mixer may also be covered.

4. The Firm shall declare the varieties of Anaesthetic Machines intended to be covered in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

5. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation, to the extent possible.

ANNEX B

List of Test Equipment

Major test equipment required to test as per the Indian Standard.

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	General, Cl 4	Lux Meter
2	Pressure Gauges and Pressure and Contents Indicators, Cl – 7	Thermometer Steel Scale Pressure gauge
3	Pressure Regulators, Cl – 8.2	Flow Meter / Rotameter Pressure gauge
4	Machine Gas Piping & Flowmeters, Cl – 9 &11	Flow Meter / Rotameter Pressure gauge
5	Oxygen Supply Failure, Cl – 17.1.2	Sound Level Meter Stop Watch
6	Cross contamination Test, Annex A	As per Cross-contamination Test Set up as given in Annex A
7	Vaporizer accuracy without applied back pressure Test, Annex B	Vaporizer accuracy without applied back pressure Test set up as given in Annex B
8	Vaporizer accuracy with applied back pressure Test, Annex C	Vaporizer accuracy with applied back pressure Test set up as given in Annex C

The above list is indicative only and may not be taken as exhaustive.

ANNEX C

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipments.

2. TEST RECORDS –The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING– In addition to the requirements of Cl 13.2.10, 13.2.11, 18 & 19 of IS 11378, each Anaesthetic Machine shall have the following information on a label affixed to it:

a) Manufacturer's name, initial or registered trade mark;
b) Code or Serial Number;
c) Month & year of manufacture.

3.1 Test Certificate – If so desired by the purchaser, each Anaesthetic Machines for use with humans shall be accompanied with test certificate which shall contain the Code or Serial Number and the corresponding test results as per IS 11378 / ISO 5358.

4. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

4.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

5. REJECTIONS– Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
4	General (except 4.3)	4	IS 11378	R	Each Unit		
4.3	Visibility of controls	4.3	IS 11378	S	Once in a year for each type/design or whenever any change is made in the control and gauges affecting their visibility.		
5 to 16	Construction, Design and features	5 to 19	IS 11378	R	Each Unit		
12.6	Test method for Cross contamination	Annex A	IS 11378	R	Each Unit		
13.2.7	Test method for vaporizer accuracy without applied back pressure	Annex B	IS 11378	R	Each Unit		
13.2.8	Test method for vaporizer accuracy with applied back pressure	Annex C	IS 11378	R	Each Unit		
13.2.9	Testing for liquid discharge	13.2.9	IS 11378	R	Each Unit		
17 (except 17.1.2)	Oxygen supply failure precautions	17	IS 11378	R	Each Unit		
17.1.2	Alarm working	17.1.2	IS 11378	R	Each Unit		
17.1.2	Alarm sound level	17.1.2	IS 11378	S	Once in a year for each type/design or whenever there is any change in the design/source of alarm system		

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: The control unit and levels of control as decided by the Bureau are obligatory to which the licensee shall comply with.

Note-3: A user instruction manual as per Clause 19 of IS 11378 shall be supplied with each anaesthetic machine.