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उत्पाद मैनुअल

श्वसन संरक्षी युक्तियां – स्वतः पूर्णबंद परिपथ श्वसन उपकरण, रसायन ऑक्सीजन (KO₂)
टाइप, स्वतः उत्पादन, स्वतः रेस्क्यूअर्स
IS 15803: 2008 के अनुसार

**PRODUCT MANUAL FOR
RESPIRATORY PROTECTIVE DEVICES – SELF CONTAINED CLOSED CIRCUIT BREATHING APPARATUS CHEMICAL
OXYGEN (KO₂) TYPE, SELF GENERATING, SELF RESCUERS
ACCORDING TO IS 15803: 2008**

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	Product	:	IS 15803: 2008
	Title	:	RESPIRATORY PROTECTIVE DEVICES – SELF CONTAINED CLOSED CIRCUIT BREATHING APPARATUS CHEMICAL OXYGEN (KO ₂) TYPE, SELF GENERATING, SELF RESCUERS
	No. of Amendments	:	03
2.	Sampling Guidelines:		
a)	Raw material	:	Raw material/components: Manufacturer to submit declaration/undertaking in compliance to cl. 5.2.1, 5.2.2 and 5.2.4. For compliance to cl. 5.2.3 test certificate/in-house report as per annex – D of IS 15803:2008 for insulation resistance of non-metallic containers to be submitted by the manufacturer
b)	Grouping guidelines	:	Manufacturer shall declare the type of Respiratory Protective Device, they intend to cover in the licence. The sample of each classification (Nominal rated duration to be declared) and material shall be subjected to testing for considering Grant of Licence/Inclusion.
c)	Sample Size	:	20 Units
3.	List of Test Equipment	:	Please refer ANNEX – A
4.	Scheme of Inspection and Testing	:	Please refer ANNEX – B
5.	Possible tests in a day	:	All tests except resistance to temperature.

6.	Scope of the Licence:	:	Licence is granted to use Standard Mark as per IS 15803: 2008 with the following scope:
	Name of product	:	RESPIRATORY PROTECTIVE DEVICES – SELF CONTAINED CLOSED CIRCUIT BREATHING APPARATUS CHEMICAL OXYGEN (KO ₂) TYPE, SELF GENERATING, SELF RESCUERS
	Material (Body)	:	Metallic Container/Non-metallic Container
	Nominal rated Duration	:	... min
	Additional Requirements (Breathing Apparatus for mining)	:	With and/or without

भारतीय मानक ब्यूरो
 BUREAU OF INDIAN STANDARDS
 मानक भवन, ९, बहादुर शाह ज़फ़र मार्ग
 Manak Bhawan, 9, Bahadur Shah Zafar Marg
 नई दिल्ली- ११०००२
 New Delhi – 110002

ANNEX – A
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. no.	Tests used in with Clause Reference		Test Equipment
	Cl. No.	Test	
1.	5.4	Mass	Weighing balance
2.	5.7	Leak tightness	<u>Leak tightness of the ready to use Apparatus</u> Apparatus with Manometer Rotameter Vacuum Gauge Pressure gauge <u>Leak Tightness of the carrying container</u> Water tank
3.	5.11	Relief Valve	Test apparatus as per F-2.1.1 (a), Breathing machine as per F-2.1.1 (b), Test gas as per F-2.1.1 (c), Humidifier Instrument capable of measuring tracer gas used such SF ₆ /any other suitable gas, arrangement to carry out test at ambient temperature and relative humidity of $27 \pm 2^{\circ}\text{C}$ and 65 ± 5 percent
4.	5.12	Breathing Bag	Breathing bag volume testing apparatus with any suitable gas meter
5.	5.13	Resistance to temperature	Oven (for 72 h in a dry atmosphere of $70 \pm 3^{\circ}\text{C}$), conditioning chamber (for 72 h at $70 \pm 3^{\circ}\text{C}$ and at 95 – 100 percent relative humidity), freezer (for 24 h at $-30 \pm 3^{\circ}\text{C}$), arrangement for walking in cold chamber and at ambient temperature as per C-3.2 with a control on oxygen and carbon dioxide content of the inhaled air
6.	5.14	Flammability	Test as per H-2 and Fig. 10 of IS 15803, Temperature indicator, Pressure gauge for adjusting gas flow, Stopwatch
7.	5.15	Mechanical Strength	<u>Shock test</u> Arrangement for a free fall from a height of 1.5 m onto a concrete floor <u>Vibration test</u> Apparatus as per J-2 and Fig 11
8.	5.16	Performance	Breathing Machine as per A-1, Apparatus Connectors (for mouthpiece), Dummy head (for full face mask), Temperature indicator (Inlet and outlet gas), arrangement to conduct Test at room temperature ($23 \pm 2^{\circ}\text{C}$) Breathing resistance measuring apparatus as per A-4

9.	5.17	Surface temperature	Temperature indicator with thermocouples (A-3, during performance test)
10.	5.2.3	Insulation resistance of non-metallic carrying container	Test apparatus as per D-1, distilled water, isopropyl alcohol, conditioning chamber
11.	5.18	Practical Performance test	Dark room as per B-3.2.1, arrangement for measurement of temperature and Relative humidity of the atmosphere at various points of the escape route as well as on the mass of ready to use apparatus, Test house as per B-3.3.1 having ambient temperature of $30 \pm 10^{\circ}\text{C}$, free of smoke and negligible air flow. Arrangement for monitoring of a) Oxygen content of inhaled gas, b) Carbon dioxide content of inhaled gas, and c) Breathing resistance. Arrangement for Escape Exercise Underground (for additional test) [The test subjects to be from persons who practice regularly with the apparatus and whose medical history is known to be satisfactory. Test subjects shall be medically examined immediately before the test and certified fit to undertake the test procedure. Each subject shall be suitably clothed during the test]

ANNEX B**Scheme of Inspection and Testing****1. QUALITY ASSURANCE PLAN**

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit i.e. Batch and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4 below.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 **Control Unit:** For the guidance of manufacturers, the recommended definition of Control Unit is: Quantity of Respiratory Devices of same variety made from the same material and manufactured under similar conditions in a day.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in-house laboratory (In-house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer, and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in-house as "R" or other tests which can be sub-contracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

They shall also implement a calibration plan for the in-house test equipment.

2.1.1 Alternatively, in lieu of an in-house laboratory, manufacturers can also utilize the

provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.2 TEST RECORDS- The manufacturers shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING – The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on RESPIRATORY PROTECTIVE DEVICES and its packaging provided always that the respiratory protective devices thus marked conforms to every requirement of the specification.

3.1 Packing and Marking shall be done as per IS 11744: 2020.

3.2 Additional Marking requirements: The apparatus and/or its package shall also be marked with the following additional requirement:

a) “For BIS certification details please visit www.bis.gov.in”

4. REJECTION - All the production which conforms to the Indian Standard and covered under scope of the licence shall be marked with Standard Mark. Disposal of non-conforming product shall be done in such a way to ensure that there is no violation of provisions of BIS Act, 2016

TABLE 1
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
5.1	Design		IS 15803		Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
5.2	Material/Components	5.2	IS 15803	S	One	Each consignment	Raw material/components used shall be declared by the manufacturer
	Insulation resistance	Annex D	IS 15803	R	One	Each Control unit	applicable if the container is non-metallic
5.3	Cleaning and Disinfection	-	IS 15803	R	Each apparatus	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity	
5.4	Mass	-	IS 15803	R	-do-		
5.5	Harness	-	IS 15803	R	-do-		
5.6	Handling	-	IS 15803	R	-do-		
5.7	Leak tightness	Annex - E	IS 15803	R	Each apparatus		
5.8	Facepiece	-	IS 15803	R	Each apparatus	Firm to have adequate in-process controls to check compliance of this parameter as per the limits and tolerances given in the Indian Standard. However, appropriate records	In case of full-face mask as facepiece, it should comply with Cl 5.8.4 (IS 14166). No testing is required if full face piece is ISI marked/ accompanied with Test Certificate

						shall be maintained by the manufacturer for evidence of conformity	
5.9	Goggles	-	IS 15803	R	Each apparatus	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity	
5.10	Inhalation and Exhalation Valves	-	IS 15803	R	-do-		
5.11	Relief Valve	Annex - F	IS 15803	R	One	Each Control unit	
5.12	Breathing Bag	Annex - G	IS 15803	R	-do-	Each Control unit	
5.13	Resistance to temperature	-	IS 15803	R	-do-	Once a week	
5.14	Flammability	Annex - H	IS 15803	R	-do-	Once a month	
5.15	Mechanical Strength	Annex - J	IS 15803	R	-do-	Each Control unit	
5.16	Performance	-	IS 15803	R	-do-	Each Control unit	
5.17	Surface temperature	-	IS 15803	R	-do-	Each Control unit	
5.18	Practical performance test	Annex - B	IS 15803	R	-do-	Once a month	
5.19	Additional requirement	-	IS 15803	R	-do-	Each Control unit	Additional Requirement is applicable for apparatus designed for special use/mining. Test is applicable if it is claimed.