PRODUCT MANUAL FOR BEHIND THE EAR (BTE) HEARING AIDS - DIGITAL ACCORDING TO IS 16127:2013

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 16127: 2013
	Title	:	Behind the Ear (BTE) Hearing Aids – Digital
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	NA
b)	**Grouping guidelines**	:	Each variety shall be tested for GoL/ CSoL
c)	**Sample Size**	:	11 nos.
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:**		
	As the licence is operated on Factory Testing basis, complete testing of a sample shall be done in factory. 1 manday is required for complete testing.		
6.	**Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 16127: 2013 with the following scope:		
	Name of the product	Behind the Ear (BTE) Hearing Aids – Digital	
	Any other aspect required as per the Standard	i. With/ without AGC ii. With/ without telecoil iii. With/ without tone control iv. Programmable/ Non-programmable	

ANNEX A

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
01	8.1.2, 8.1.3 & 8.2 Table 1 (i-ix)	Hearing Instrument Analyzer & Test System
02		Test Chamber Sound proof chamber that encloses the instrument to be tested
03		Test Chamber Cable Connects the Test Chamber to the Hearing analyzer with coupler
04		Ear-Level Adapter (BTE) Snaps into the 1/4" (6.35 mm) diameter cavity of the Hearing Analyzer
05		Sound Level Calibrator
06		Microphone Adapter
07	5.3.3	Digital Weighing Scale
08	5.3.2	Vernier Caliper
09	5.3.2	Micrometer
10	8.1.2(g)	Battery Substitution Pill
11	8.2, Table 1	Heating Chamber or Incubator

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

ANNEX B

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 equipment.

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

3. LABELLING AND MARKING – As per the requirements of IS 16127:2013

4. CONTROL UNIT – BTE Digital Hearing Aids manufactured in a day shall constitute a control unit.

5. 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.

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

6. 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 Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Ref**				
5.1	Design and Workmanship	5.1	IS 16127	R	Each Hearing Aid		--
5.2	Power Supply	5.2	IS 16127	R			--
5.3	Housing	5.3	IS 16127	R			--
5.3.1	Battery Compartment & Ear Insert	5.3.1	IS 16127	R			--
5.3.2	Dimensions	5.3.2	IS 16127	R			--
5.3.3	Mass	5.3.3	IS 16127	R			--
5.4	External Case	5.4	IS 16127	R			--
5.5	Controls	5.5.1, 5.5.2, 9.12	IS 16127	R			--
8.1.2.a, 8.1.3. a	Maximum Saturation Sound Pressure level (OSPL 90)	8.1.2 (a) & 8.1.3 (a)	IS 16127	R			--
8.1.2.b, 8.1.3.b	HF Average OSPL 90	8.1.2 (b) & 8.1.3(b)	IS 16127	R			--
8.1.2.d, 8.1.3.c	HF – average full-on gain (at 50/60 dB input)	8.1.2 (d) & 8.1.3(c)	IS 16127	R			--
8.1.2.c, 8.1.3. d	Frequency range	8.1.2 (c) & 8.1.3(d)	IS 16127	R			--
8.1.2.e, 8.1.3. e	Total Harmonic Distortion	8.1.2 (e) & 8.1.3(e)	IS 16127	R			--
8.1.1 & 8.2 (Table 1)	Induction Coil Sensitivity (at 10mA/m) (if telecoil is provided)	8.1.1 & Table 1 (viii)	IS 16127	R			--

8.1.2. f	Internal noise from the hearing aid in terms of equivalent input noise level	8.1.2 (f)	IS 16127	R	one	Each control unit	--
8.1.2. g	Battery Current	Clause 7.4	IS 16127	R	one	Each control unit	--
8.1.1 & Table 1 (v)	Effect of Tone control positions on Frequency Range	8.1.1 & Table 1 (v)	IS 16127	R	one	Each control unit	--
8.1.1 & Table 1 (ix)	AGC Characteristics (if applicable)	8.1.1 & Table 1 (ix)	IS 16127	R	one	Each control unit	--
8.1.1 & Table 1 x(a)	Environmental tests: Climatic tests, dry heat at 40 °C for 2 h	8.1.1 & Table 1x(a)	IS 16127	R	one	Each control unit	--
8.1.1 & Table 1 x(b)	Environmental tests: Drop test	8.1.1 & Table 1 x(b)	IS 16127	R	one	Each control unit	--

Note: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.