



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 318869 Evertone Pty Ltd - Audiometer, auditory evoked response

ARTG entry for Medical Device Included Class IIa
Sponsor Evertone Pty Ltd
Postal Address 15/51-53 Spring Street Bondi Junction, BONDI JUNCTION, NSW, 2022
 Australia
ARTG Start Date 13/06/2019
Product category Medical Device Class IIa
Status Active
Approval area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Neurosoft LLC	5 Voronin Str Ivanovo, Russian Federation, 153032 Russian Federation

Products

1. Audiometer, auditory evoked response

Product Type	Single Device Product	Effective date	13/06/2019
---------------------	-----------------------	-----------------------	------------

GMDN 35747 Audiometer, auditory evoked response

Intended purpose Neuro-Audio perform the following tests

1. Auditory brainstem response (ABR)/Brainstem evoked response audiometry (BERA) (air and bone conduction) including EABR
2. Vestibular evoked myogenic potentials (VEMP)
3. Electrocochleography (EcochG)
4. Auditory steady-state response (ASSR) with possibility of simultaneous stimulation at 4 frequencies for both ears (multi-ASSR)
5. Transient evoked otoacoustic emission (TEOAE)

Specific Conditions

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary