Public Summary

Summary for ARTG Entry: 140659 RITM Australia Pty Ltd - Stimulator, electrical, analgesic, peripheral nerve, transcutaneous

ARTG entry for	Medical Device Included Class IIa
Sponsor	RITM Australia Pty Ltd
Postal Address	44 Gould Ave, ST IVES, NSW, 2075 Australia
ARTG Start Date	20/06/2007
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
RITM OKB ZAO	99 Petrovskaya Street TAGANROG, , 347900 Russian Federation

Products

1. Stimulator, electrical, analgesic, peripheral nerve, transcutaneous

Product Type	Single Device Product	**Effective date**	20/06/2007

GMDN	35372 Analgesic TENS system
Intended purpose	The device is intended to be used a an analgesic peripheral nerve stimulator, to be placed on the skin and is used to treat pain associated with surgery, trauma, musculoskeletal problems, bursitis or dental problems. It may also be used in physical therapy and during labour/delivery

Specific Conditions

The following product specific conditions are to take effect on 10 February 2017

1. This medical device ARTG inclusion is limited to some medical devices of the kind.
· These devices of the kind are medical devices identified by the manufacturer as:
- SCENAR Sport D (Serial Number 12553);
- SCENAR Sport (Serial Number 44007);
- SCENAR Home (Serial Number 44007);
- SCENAR Pro Plus (Serial Number 11256);
- SCENAR Pro (Serial Number 11256).
· Other devices of the kind must not be supplied under this ARTG entry in Australia.

2. In addition to the condition in paragraph 1, the person in relation to whom the kind of medical device is included in the ARTG (the sponsor) must provide to the Therapeutic Goods Administration, Department of Health (the TGA) a copy of new conformity assessment certification. The Certificate must appropriately (including the scope and conformity assessment procedure) cover the kind of medical device in this ARTG entry, and must be issued by either the TGA or by a Notified Body, designated by one of the European countries to assess the conformity with the Council Directive 93/42/EEC Medical Devices.
· This Certificate must be provided to the TGA as soon as possible but no later than 31 December 2017.

3. The abovementioned information must be provided to the TGA, at the following email address: postmarketdevices@tga.gov.au (or any other address if notified by the TGA).
- The sponsor will be required to submit an application for Manufacturer's Evidence to provide a new Certificate. Further if the sponsor requires a variation to the ARTG entry to include details of the medical devices that are to be imported, supplied or exported under an entry, the sponsor will need to submit a Device Change Request to the TGA.

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