Australian Government

Department of Health

Therapeutic Goods Administration

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 used for delivering non-invasive therapeutic treatment on the skin to regulate physiologic systems of the body in order to relieve and manage different pain-related pathologies.

Specific Conditions

The following product specific conditions are to take effect on 30 April 2018

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:
± CHANS-SCENAR (Trade names RITMSCENTAR Home, SCENAR Home);
± CHANS-01-SCENAR (Trade names RITMSCENAR Sport, SCENAR Sport, SCENAR Pain Genie, RITMSCENAR Home Device, RITMSCENAR Gorfinkel, SCENAR Gorfinkel);
± CHANS-02-SCENAR (Trade names RITMSCENAR Basic, SCENAR Basic);
± CHANS-SCENAR-M (Trade names RITMSCENAR Home D, SCENAR Home D);
± CHANS-01-SCENAR-M (Trade names RITMSCENAR Sport D, SCENAR Sport D);
CHANS-02-SCENAR-M (Trade names RITMSCENAR Basic D, SCENAR Basic D);
± SCENAR-1-NT (VERSION 01) (Trade names RITMSCENAR Pro Prime, SCENAR Pro Prime);
± SCENAR-1-NT (VERSION 02.1) (Trade names RITMSCENAR Pro Plus, RITMSCENAR Pro+, SCENAR Pro Plus, SCENAR Pro+);
± SCENAR-1-NT (VERSION 02.2) (Trade names RITMSCENAR Pro Optima, SCENAR Pro Optima);
± SCENAR-1-NT (VERSION 02.3) (Trade names RITMSCENAR Pro, SCENAR Pro);
± SCENAR-1-NT (VERSION 03) (Trade names RITMSCENAR Pro Essential, SCENAR Pro Essential);
± SCENAR-1-NT (VERSION 01C) (Trade names RITMSCENAR Pro Prime C, SCENAR Pro Prime C, RITMSCENAR Super Pro v.2, bioSCENAR Professional v.2);
± SCENAR-1-NT (VERSION 02.1C) (Trade names RITMSCENAR Pro Plus C, RITMSCENAR Pro +C, SCENAR Pro Plus C, SCENAR Pro +C);
± SCENAR-1-NT (VERSION 02.2C) (Trade names RITMSCENAR Pro Optima C, SCENAR Pro Optima C, SCENAR Physio);
± SCENAR-1-NT (VERSION 02.3C) (Trade names RITMSCENAR Pro C, SCENAR Pro C);
± SCENAR-1-NT (VERSION 03C) (Trade names RITMSCENAR Pro Essential C, SCENAR Pro Essential C).
· Other devices of the kind must not be supplied under this ARTG entry in Australia.

Note: If the sponsor requires a variation to the ARTG entry to include further 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.

Note: These additional conditions imposed on the kind of device are in addition to any other conditions imposed on the ARTG entry and conditions applying automatically under the Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Devices) Regulations 2002.

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