

Record Summary	233764	Herbresearch Pty Ltd - Hyperthermia system, radio frequency
Sponsor	Herbresearch Pty Ltd	
Therapeutic Type	Medical Device	
Product Category	Included Class IIb	
ARTG Start date	13/02/2015	
Postal Address	29 MacFarlane Street, SOUTH HOBART, TAS, 7004 Australia	
Billing Address	29 MacFarlane Street, SOUTH HOBART, TAS, 7004 Australia	

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	Certificate number(s)
Celsius42 GmbH	Hermann-Hollerith-Str 11 , Eschweiler, 52249 Germany	DV-2014-MC-19907-1

Products

1.Hyperthermia system, radio frequency

Product Type	Medical device system	Status	Current
		Effective date	13/02/2015

GMDN	40782 Hyperthermia system, radio frequency
Functional description	Not included on record
Intended purpose	The Celsius TCS radiofrequency loco-regional hyperthermia system is intended to heat a region of the body to stimulate metabolism, support the immune system and to treat tumours in conjunction with chemotherapy and/or radiotherapy in order to optimise the effect of these therapies.

Variant information

Device Information

12 Diagnostic and therapeutic radiation devices

Specific Conditions

No Specific Conditions included on Record