



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	302821	BTL Medical Technologies Pty Ltd - Deep-tissue electromagnetic stimulation system, professional
ARTG entry for	Medical Device Included Class IIa	
Sponsor	BTL Medical Technologies Pty Ltd	
Postal Address	Unit 5, 10 Enterprise Close, West Gosford, NSW, 2250 Australia	
ARTG Start Date	10/05/2018	
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
BTL Industries Limited	161 Cleveland Way Stevenage, Hertfordshire, SG1 6BU United Kingdom

Products

1 . Deep-tissue electromagnetic stimulation system, professional			
Product Type	Single Device Product	Effective Date	10/05/2018
GMDN	58762 Deep-tissue electromagnetic stimulation system, professional		
Intended Purpose	The device is intended to provide pelvic floor muscle strengthening for treatment of genitourinary system diseases/disorders such as urinary incontinence, urinary incontinence after radical prostatectomy, female sexual dysfunction, erectile dysfunction, postpartum pelvic floor dysfunction and pelvic pain syndrome in male and female patients.		

Specific Conditions
No Specific Conditions included on Record

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