



Australian Government

Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Symbiotic Devices Pty Ltd**

for approval to supply

## **Symbiotic Devices Pty Ltd - Quantitative sensory tester, neuropathology diagnosis**

<b>ARTG Identifier</b>	233399
<b>ARTG Start date</b>	4/02/2015
<b>Product Category</b>	Medical Device Included Class IIa
<b>GMDN</b>	37349
<b>GMDN Term</b>	Quantitative sensory tester, neuropathology diagnosis
<b>Intended Purpose</b>	A computerized device intended for the quantitative assessment of large nerve fiber dysfunction, designed for both clinical and advanced research applications. It measures sensory thresholds for vibration. These thresholds deviate from the normal range in diabetic neuropathy and peripheral nerve diseases. Referred to as Vibration Testing. This method is useful as an aid in early diagnosis, followup, and therapy assessment.

Manufacturer Details	Address	Certificate number(s)
Medoc Ltd Advanced Medical Systems	Ha'Dekel Street 1 Ramat Yishai, , 30095 Israel	DV-2014-MC-18794-1

### **ARTG Standard Conditions**

The above Medical Device Included Class IIa has been entered on the Register subject to the following 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.

### **Products Covered by This Entry**

- 1. Quantitative sensory tester, neuropathology diagnosis**

### **Product Specific Conditions**

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