

TGN

THERAPeutic  
GOODS  
ADMINISTRATION

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Commonwealth Department of  
Health and  
Ageing

**CERTIFICATE FOR INCLUSION OF A MEDICAL  
DEVICE**

ARTG Number 107117

ARTG Labelname Heine Aust Pty Ltd - Otoscope

Sponsor Heine Aust Pty Ltd

Commencement 26/08/2004

Date

Manufacturer HEINE OPTOTECHNIK GMBH & Germany  
CO KG

Device Class Class 1

GMDN Code 12849 Otoscope

ARTG Product Number and Name  
186140 Otoscope

**The above Medical Device is Included in the Australian Register of Therapeutic Goods subject to the following conditions**

**Standard Conditions**

*The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.*

*The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are set out in paragraphs 62 to 67.*

*For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is*

CERTIFIED ORIGINAL  
CERTIFICATE  
WHEN RED