

TGN
**THERAPEUTIC
GOODS
ADMINISTRATION**
PO Box 100, Woden, ACT 2606, Australia
Telephone: (02)6232 8444, Fax (02)6232 8241
ABN 40 939 406 804



Commonwealth Department of
**Health and
Ageing**

CERTIFICATE FOR INCLUSION OF A MEDICAL DEVICE

ARTG Number 107278

ARTG Labelname Heine Aust Pty Ltd - Ophthalmoscope, direct

Sponsor Heine Aust Pty Ltd

**Commencement 31/08/2004
Date**

**Manufacturer HEINE OPTOTECHNIK GMBH & Germany
CO KG**

**Device Class Class 1
GMDN Code 12817 Ophthalmoscope, direct**

**ARTG Product Number and Name
186434 Ophthalmoscope, direct**

**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