Public Summary

Summary for ARTG Entry: 220289 HealthScreen Solutions Pty Ltd - Clinical chemistry autoimmune IVDs

ARTG entry for	Medical Device Included - IVD Class 2
Sponsor	HealthScreen Solutions Pty Ltd
Postal Address	PO Box 615, CHURCH POINT, NSW, 2105 Australia
ARTG Start Date	20/02/2014
Product category	Medical Device Class 2
Status	Active
Approval area	IVD

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 as set out in the following paragraphs.,

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 provided in such a way as to allow the sponsor to be identified.,

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.,

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.,

Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.,

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.,

It is a condition of inclusion in the ARTG that the sponsor of a medical device that is a Class 4 IVD provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year.,

Goods which would require an application audit under Regulation 5.3 if subject to a separate application for entry in the Register cannot be included under this ARTG entry until a request to vary the entry has been submitted and approved by the TGA.

Manufacturers

Name	Address
Augurix SA	Route de L'ille-au-Bois 1A Monthey, , 1870 Switzerland

Products

1. Clinical chemistry autoimmune IVDs

Product Type	IVD	**Effective date**	20/02/2014

GMDN	CT869 Clinical chemistry autoimmune IVDs
Intended purpose	Simtomax® is intended to be used as a first line screening test to diagnose Celiac Disease and IgA deficiency. Testing must always be performed prior to introducing a gluten free diet. The diagnosis must be confirmed with an intestinal biopsy.