Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

FPA Australia Pty Ltd

for approval to supply

FPA Australia Pty Ltd - Vinyl examination/treatment glove, non-powdered

ARTG Identifier	223757
ARTG Start date	24/05/2014
Product Category	Medical Device Included Class 1
GMDN	47176
GMDN Term	Vinyl examination/treatment glove, non-powdered
Intended Purpose	Vinyl examination gloves can be powdered or non-powdered, depending on your preference. Since they don't have a snug fit like latex or nitrile gloves, vinyl examination gloves don't typically cause the moisture retention that can be a problem with the other types of gloves. In addition, they have no rubber proteins, and are a perfect match for anyone that has a reaction to latex. It is important to keep in mind that they are also much thinner and much more prone to tearing, puncturing, and ripping than latex or nitrile gloves, so they are not recommended in high risk areas. For home health care professionals or nurses working with patients without fear of body fluid contact, vinyl examination gloves are a perfect option. They are low cost, and can be used as needed and disposed afterwards. They are also a great way to help keep the skin on your hands in great shape, since you can avoid the multiple washes between patients. Instead, you simply toss out the gloves and slip on a new pair before working with the next patient. If you make this a habit, you also don't have to worry about cross contamination, as your hands are always protected and clean.

Manufacturer Details	Address	Certificate number(s)
Jiangsu Jaysun Glove Co Ltd	199 Jianling Road Economic Developing-Area Siqian City, Jiangsu Province, China - Peoples Republic of	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- 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.,
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class III or implantable Class IIb 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. For orthopaedic implant prosthesis that have been re-classified from Class IIb to Class III medical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class IIb to Class III; and/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class III medical device on the ARTG.,

- 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.,
- 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.

Products Covered by This Entry

1. Vinyl examination/treatment glove, non-powdered

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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ARTG Start Date: 24/05/2014