Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ARTG Certificate

Issued to

Morton Surgical Pty Ltd T/A Matrix Surgical Company

for approval to supply

Morton Surgical Pty Ltd T/A Matrix Surgical Company - GLUBRAN 2 - Adhesive, soft tissue approximation

ARTG Identifier	**158438 Class III**
ARTG Start date	**13/01/2009**
Product Category:	**Medical Device Included Class III**
GMDN	**34164**
GMDN Description	**Adhesive, soft tissue approximation**
Intended Purpose	**For use as a surgical glue to exert an adhesive and haemostatic action on tissues. Can be used in open and laparoscopic surgery and in treatments in digestive tract endoscopy, interventional radiology and vascular neuroradiology. It may be applied alone or in combination with sutures. For use in a wide variety of surgical procedures, e.g. Cardiac surgery, Paediatric cardiac surgery, Vascular surgery, Neurosurgery, ENT surgery, Paediatric surgery, General surgery, Thoracic surgery, Gynaecological surgery, Digestive tract endoscopy, Interventional radiology and vascular neuroradiology, Urological surgery etc.**

Manufacturer(s) Details	Address	Manufacturing steps
Gem SRL	Via dei Campi 2 Viareggio, , 55049 Italy	

ARTG Standard Conditions

The above Medical Device Included Class III has been entered on the Register subject to the following 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.
- 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 Devices, Blood and Tissues, 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 received by the manufacturer relating to problems with the use of the device that have been received by them over the year.
- 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.

Products covered by this Entry

1. GLUBRAN 2 - Adhesive, soft tissue approximation

Functional description

GLUBRAN 2 is a synthetic cyanoacrylic surgical glue with haemostatic & adhesive properties. It is a pale yellow, transparent liquid ready for use and polymerises rapidly on contact with tissue & in moist environments, to create a thin waterproof elastic film of high tensile strength. The glue starts to set after 1-2 sec & reaches max mechanical strength after 60-90 sec. The glue is eliminated by hydrolytic breakdown. The polymerization reaction generates a temperature of approximately 45?C.

Variant Information

Description	Range
Nil variant (as 1 device)	6 x 1mL single dose vials

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

No specific indications have been recorded against this entry.

END OF CERTIFICATE

ARTG Certificate