Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-2018-LI-13190-1

Granted to:

Surgical BioFix Ltd
ABN: 99 117 873 462

Manufacturing Site Address:

28 Harries Road
Coorparoo QLD 4151

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Human Tissue	Sterile	Not Applicable	Amnion Membrane Allograft	Collection
Human Tissue	Sterile	Not Applicable	Amnion Membrane Allograft	Processing
Human Tissue	Sterile	Not Applicable	Amnion Membrane Allograft	Storage on site
Human Tissue	Sterile	Not Applicable	Amnion Membrane Allograft	Release for supply

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989*.

No additional specific conditions have been imposed on this licence under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989* and consequently this licence does not have a Part 2.

Originally Granted: **13 May 2020** Date Revised: **N/A**

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TGA Health Safety Regulation