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Manager of Company Announcements  
Australian Stock Exchange Limited  
Level 6, 20 Bridge Street  
NSW 2000  
By E-Lodgement

## **US AUTOMATED ASSEMBLY SYSTEM NOW OPERATIONAL**

- 1. Completion and successful testing of US automated assembly line**
- 2. 1mL Unitract Insulin Syringe regulatory approvals pending**

A demonstration of the automated assembly system operating at our US facility, and a copy of an article featured on the front cover of the September edition of 'Medical Design Technology', a leading US industry magazine, are available for viewing at [www.unilife.com.au](http://www.unilife.com.au).

### **1. Completion and successful testing of US automated assembly line**

Unilife Medical Solutions Limited ("Unilife") (ASX: UNI) is pleased to announce the successful testing of its fully automated assembly line developed for the manufacture of the Unitract™ range of 1mL syringes at its US facility, Integrated BioSciences Inc ("IBS")

This milestone is the result of 16 months of development work undertaken by Unilife and IBS, and marks the first time a Unilife product has been assembled at its US facility using US-manufactured components. This new automated production system developed for the assembly of Unitract 1mL syringes is also highly flexible, and will share the same production platform design which will be used for the assembly of other related safety products such as the Unilife Prefilled Syringe and the MedPro Blood Collection devices.

The system incorporates 100% inspection and assembly verification throughout all stages of the production sequence. Twenty-two fully networked high speed machine vision inspection cameras examine every component during the assembly process, and report correct placement and positioning within the syringe assembly.

Following the completion of all verification tests, Unilife will transfer the automated assembly system into the certified cleanroom for qualification. The Needle Overmould (NOM) assembly section has already been installed in this cleanroom facility, where it is operational and being used to supply stock for the semi-automated assembly of 1mL Unitract syringes by KDL in China.

**Unilife Medical Solutions Limited**

Level 5, 35 Clarence Street, Sydney NSW 2000 T +612 8346 6500 F +612 8346 6511 W [www.unilife.com.au](http://www.unilife.com.au) ABN 14 008 071 403

The qualification phase will be completed by the end of the first quarter in 2008. The commencement of high volume US production will coincide with US regulatory approval and other US launch activities.

The robotic assembly system is rated for the automated production of between 35 and 40 million syringes per annum, with an upgrade program now being implemented that could increase longer term capacity up to 70 million units per annum.

The 1mL assembly system developed at Unilife's US facility consists of four distinct sections, each of which is designed to ensure that production occurs in a highly flexible, continuous process. These sections, all of which have now been individually tested, are the:

- a) Needle Overmould (NOM) system, featuring a state of the art micro-moulding process jointly developed with leading moulding machine manufacturer, Battenfeld of Austria.
- b) Barrel Assembly Sub-System, featuring eight separate robotic stations to assemble five key components including the NOM.
- c) Plunger Assembly Sub-System, incorporating seven robotic stations to assemble the other product components into one integrated unit ready for insertion into the barrel.
- d) Final Assembly Sub-System, which uses a single robot to combine the Barrel and Plunger Assembly sections to create the finished syringe ready for bulk packaging.

Mr Keith Bocchicchio, Vice President of Technology at IBS, said:

“All identified risk factors in the fully automated assembly of the Unitract range of 1mL syringes have now been overcome, with the system capable of producing these products at desired levels of precision. With final conditioning activities now underway, we should be in a position to complete the qualification and commissioning of the system within its designated cleanroom facility during early 2008.

“IBS is delighted with the current status of the production systems which have been developed to manufacture the Unitract range of 1mL syringes. Several highly innovative engineering technologies have been devised to optimise levels of product quality and reliability. In particular, we are pleased to have created a state-of-the-art micro-moulding system that has significantly improved the production of the needle overmould component. As the ability to assemble the needle overmould was one of the major difficulties encountered with the original assembly line developed in Australia, this micro-moulding system demonstrates the automated production expertise of Unilife.”

Mr John Kelly, Chief Operations Officer at Unilife, said:

“A key question facing Unilife in recent years has been its ability to develop an automated assembly system that is capable of delivering the high-volume production of our Unitract range of 1mL syringes. Following successful testing of the 1mL assembly system at our US facility, I am pleased to report that this challenge has now been addressed.

“The relocation and qualification of injection moulding tooling from Australia to the New York facilities of Tessy Plastics and the development of the NOM micro-moulding system, has caused some delays. Now that these challenges have been overcome, Unilife is in a strong position to move towards US based production. Many of the engineering solutions which have been developed and integrated into this 1mL assembly system will also have significant additional value to the company, as they will provide technology platforms supporting other Unilife products, in particular, the on-going industrialisation of the Unitract Prefilled Syringe.”

## **2. 1mL Insulin Syringe regulatory approvals pending**

Unilife is pleased to announce that it has successfully undergone the annual surveillance audit, carried out by TUV (<http://www.tuv.com>) as required by our Quality Management Systems to ensure ongoing compliance to ISO 13485 and current device regulatory approvals. Following the completion of this audit, Unilife is pleased to announce the following regulatory deliverables:

- The approval of the Unitract Insulin Syringe for Europe (CE marking), Canada and Australia are all now pending.
- Tessy Plastics are now officially approved for supply of 1mL components following the rationalisation of operations in Australia.
- IBS has now been included as an approved manufacturer on Unilife’s certificate

With Tessy Plastics now approved for the supply of components for the Unitract range of 1mL syringes, Unilife will commence a series of product builds at KDL in China from October 15 using these US produced components. It is anticipated that these builds will be completed by the end of November, allowing for full production of both syringes to immediately commence at KDL.

KDL-assembled products will be used to fulfil initial sales orders and support other international market development activities prior to the start of full high-volume production commencing at IBS in April 2008.

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### **Shareholder / Analyst Enquiries:**

Alan Shortall or  
Jeff Carter

Unilife Medical Solutions Limited  
(02) 8346 6500

### **About Unilife**

Unilife Medical Solutions Ltd is an ISO 13485 certified developer and supplier of innovative sharps safety products, marketed under its premium Unitract™ brand, designed for use within healthcare and pharmaceutical markets. A publicly listed company on the Australian Stock Exchange (ASX:UNI), Unilife has its corporate headquarters in Sydney, Australia and has a wholly-owned subsidiary in the US State of Pennsylvania, Integrated BioSciences Inc (IBS), which is an established contract manufacturer of medical devices with FDA certified cleanroom facilities.