

The Manager  
Companies Announcement Platform  
SIM Venture Securities Exchange  
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## First Commercial Batch of SoloFlow<sup>®</sup> Complete

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### HIGHLIGHTS:

- **Five-year accelerated-aging test validates shelf-life of SoloFlow<sup>®</sup>: performance of SoloFlow<sup>®</sup> effective and safe after 5-year shelf-life**
  - **First commercial batch of SoloFlow<sup>®</sup> complete and ready for dispatch**
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Telezon Limited<sup>®</sup> ("the Company") is pleased to announce to the market the successful completion of its first commercial batch of SoloFlow<sup>®</sup> Medical Transfer Cannula.

This first commercial batch is now ready for shipping to fulfill the initial order for Serum Institute of India for use in clinical trials. The Company is finalising the required regulatory documentation before the initial lot can be released, with the first shipment due for dispatch in Week 4 of January 2012.

In addition to the completion of this first batch, the five-year accelerated-aging and subsequent mechanical testing has been completed. The five year accelerated aging was the final task to be completed to conclude the product design verification and validation of the SoloFlow<sup>®</sup> cannula.



*Image: First commercial batch of SoloFlow<sup>®</sup> Transfer Cannula ready for shipping*

Manufacturers of medical devices must demonstrate that the product, in combination with its packaging components, performs efficiently, safely and effectively throughout its intended shelf life. Accelerated-aging must be performed prior to distribution of the product. A standardised industry test has been used to accurately evaluate the environmental effect of storage on a package or product during the SoloFlow<sup>®</sup> cannula expected usable shelf life.

The relevant testing of the packaging and product demonstrates that the SoloFlow<sup>®</sup> cannula still performs efficiently and safe after a shelf-life of five years.

**TABLE 1:** Completed and Scheduled Activities for *SoloFlow*<sup>®</sup> Medical Transfer Cannula

ACTIVITY	STATUS
First samples manufactured for world market	 <b>Completed Oct 2010</b>
Cap mould qualification – purpose is to rigorously test the process to determine capability of consistent production that meet specifications	 <b>Completed Nov 2010</b>
Mechanical testing	 <b>Completed Feb 2010</b>
Signed MOU for commercial placement with Serum Institute of India	 <b>Completed Mar 2011</b>
Cap mould validation – purpose is to confirm moulding process meets pre-determined specifications and quality attributes, delivering an approved cap fabrication process for commercial production.	 <b>Completed Apr 2011</b>
Needle mould qualification - purpose is to rigorously test the process to determine capability of consistent production that meet specifications	 <b>Completed Apr 2011</b>
4000 needles produced and assembled with cap to be sent for packaging verification and validation.	 <b>Completed May 2011</b>
Biological qualification of <i>SoloFlow</i> <sup>®</sup> Polymer Draw-up Needle – purpose is to evidence that materials are biological compatible with necessary standards	 <b>Completed Aug 2011</b>
FDA registration of <i>SoloFlow</i> <sup>®</sup> Polymer Draw-up Needle	 <b>Completed early Oct 2011</b>
Accelerated age tests – purpose is to verify the products expiry date and shelf life	 <b>Completed Oct 2011</b>
Five year accelerated age test - – purpose is to verify the products expiry date and shelf life	 <b>Completed Jan 2012</b>
Packaging verification and validation – purpose is to confirm packaging process meets pre-determined specifications and quality attributes, delivering an approved packaging fabrication process for commercial production.	 <b>Completed Nov 2011</b>
Final product inspections by manufacturer and Telezon	 <b>Completed Dec 2011</b>
Successful first commercial batch produced	 <b>Completed Jan 2012</b>
Initial shipment to Serum Institute of India	Scheduled for Week 4 Jan 2012

1. <i>ACTIVITY:</i>	Maintenance of several Company patents across its product and technology portfolio
<i>STATUS:</i>	<b>ALL CURRENT</b>

2. <i>ACTIVITY:</i>	Registration of three trademarks: <ul style="list-style-type: none"> <li>- CoreIT® Technology in China</li> <li>- SoloFlow® in Australia</li> <li>- Telezon® in Australia &amp; international registration</li> </ul>
<i>STATUS:</i>	<b>ACCEPTED</b>
<i>DETAILS:</i>	The Company has received confirmation that the above trademarks have been accepted by the aforementioned countries.

Please refer to our new website at [www.telezon.com](http://www.telezon.com) for a more detailed look at Company's product and technology portfolio.

For and on behalf of Telezon Limited,

Dr Michelle Carr  
 Director & Co.Secretary  
 Telezon Limited

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