

Job No. 20410: Teva Isolator  
Getinge Engineer: D Yeomans  
4<sup>th</sup> & 5<sup>th</sup> January 2011

Work undertaken:

- Prior to checks/tests the isolator was relocated to final agreed position and the Equinox Isofit Pump plus a Printer were fitted.

Checks/tests:

- Service connections checked.
- Isolator inspected to confirm no damage, etc. during transit or installation
- Start-up procedure completed (in accordance with section 9 of Installation Manual)
- Air pressure adjusted to 10m<sup>3</sup>/hr flowrate in H<sub>2</sub>O<sub>2</sub> line.
- A full system pressure check was performed.
- Pump calibrated for H<sub>2</sub>O<sub>2</sub>
- Test cycles run:
  - Aeration cycle.
  - Transfer Hatch: Biodecontamination cycle (using deionised water).
  - Full system: Biodecontamination cycle (using deionised water).

Notes:

- Checks/tests performed were witnessed by Teva's representative (D Humphreys).
- Raw data (machine print-outs, etc.) were left on site.
- All tests resulted in criteria being met. There were no failures and the Isolator was left in full working order.
- A 'General Service Worksheet' No.96166 was completed by the Engineer and duly signed, as confirmation and acceptance of successful pre-commissioning, by D Humphreys.
- Training of local (Teva) staff did not take place. It was agreed that this would be deferred until a later date.

Signed ..... *Dan Yeomans* .....  
Dan Yeomans (Getinge Engineer)