

## PRODUCT CERTIFICATE

Product: Contec Hydropure - Sterile 6% H<sub>2</sub>O<sub>2</sub>  
 Product Code: SBT16HPW  
 Product Description: v/v 6% Hydrogen peroxide and 94% Water for injection  
 Batch Number: 130900172  
 Manufacture Date: 09/2013  
 Expiry Date: 09/2015

### ANALYSIS

Test:	Specification:	Results:
Colour:	Colourless	Complies
Clarity:	Clear	Complies
Filtration:	Filtered to 0.2 microns	Complies
Endotoxins:	<0.25 EU/ml	Complies
SG at 20°C:	1.021 to 1.023	1.022
Concentration of H <sub>2</sub> O <sub>2</sub> :	6,0% to 6,9%	6,90%

Manufacturer product via a Quality System certified to ISO 9001, tested in accordance with documented quality procedures and approved when required specifications are met

### IRRADIATION

	Specification:	Results:
Irradiation Dose Routine B (KGy):	Between 44.9 to 89.7	49.5

We certify that the notified goods have undergone irradiation by exposure to  $\gamma$  (Gamma) irradiation with an exposure of not less than 25 kGy to conform to European Pharmacopoeia.

Irradiation treatment applied was accordance with:

- ISO 9001: Quality Management System
- ISO 13485: Quality Management System – Medical Devices
- ISO 11137: Sterilisation of Healthcare Products – Requirements for Validation and Routine Control – Radio sterilisation
- ISO 14001: Environmental Management System

### STERILITY

Sterility test result: Complies

Test method as described in the current edition of the European Pharmacopoeia: § 2.6.1

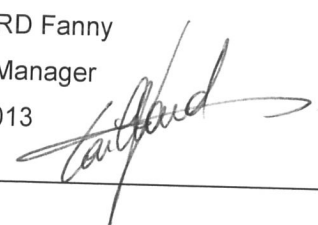
### CONFORMITY

BATCH  CONFORM  NON-CONFORM

Name: CAILLARD Fanny

Position: Quality Manager

Date: 11/19/2013

Authorised Signature: 

For and on behalf of Contec®