

## CERTIFICATE OF CONFORMITY

**PRODUCT:** InSpec AN 900ML Trigger

**PRODUCT CODE:** ANWFI20-900ML

**PRODUCT DESCRIPTION:** Sterile Diamine Cleaner

**BATCH NUMBER:** 029133

**MANUFACTURING DATE:** Oct 2013

**EXPIRY DATE:** Sept 2015

**IRRADIATION NUMBER:** S11068219-1-1

**IRRADIATION DOSE:** 25kGy's to 45 kGy's

**STERILITY TEST REF:** 60061211

**CERTIFICATE OF ANALYSIS No:** 029133

**PRODUCT TEST RESULT:** Certified that the goods listed above have been inspected, and unless otherwise stated conform in all respects to the requirements of the product specification.

APPROVAL	
APPROVED BY	<i>Kevan Hamon</i>
POSITION	<i>FACILITY OPERATOR</i>
DATE	<i>3RD DEC 13</i>

## CERTIFICATE OF ANALYSIS

**PRODUCT:** InSpec AN 900ML Trigger

**PRODUCT CODE:** ANWFI20-900ML

**PRODUCT DESCRIPTION:** Sterile Diamine, Disinfectant Cleaner

**BATCH NUMBER:** 029133

**MANUFACTURING DATE:** Oct 2013

**EXPIRY DATE:** Sept 2015

PRODUCT ASSESSMENT		
<b>FILTRATION:</b>	0.2 micron in line filter	PASS
<b>COLOUR:</b>	Colourless Liquid	Pass
<b>ODOUR:</b>	Typical	Pass
<b>CLARITY:</b>	Clear	Pass

APPROVAL	
APPROVED BY	<i>Keith Hansen</i>
POSITION	<i>FACILITY OPERATOR</i>
DATE	<i>3RD DEC 13</i>



<http://www.synergyhealthplc.com>

## Certificate of Irradiation

Date Issued: 04-Nov-2013

UK32S11068219-1-1

This is to certify that Bradford Synergy Health PLC has where appropriate delivered an irradiation process in accordance with:

EN ISO 11137-1:2006 Sterilisation of Health Care Products  
 EN ISO 9001:2008 Quality Management System  
 EN ISO 13485:2012 Quality System - Medical Devices

Redditch Medical  
 Discovery 2  
 2 William Armstrong Way  
 Net Park  
 Sedgefield  
 Co.Durham TS21 3FH  
 UNITED KINGDOM

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### Order Information

Account Number:	101254
Synergy Health Sales Part Reference:	1004283
Customer Reference Number:	P0008212
Product Description:	INSPEC IPA 1 LTRE TRIGGER 25-45KGY
Validation Reference:	4.1372
Quantity Received:	160
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	80 X LOT 029133 , 80 X LOT 029130 , 3 PLTS WEDS 30.10.13

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### Irradiation Data

Date and Time of Irradiation:	02-Nov-2013 19:40
Reference Dose Range kGy:	33.4 - 33.6
Calculated Minimum Dose kGy:	29.6
Calculated Maximum Dose kGy:	36.4

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Irradiation Release Authorised By Synergy Health plc

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Registered Office: Ground Floor Stella, Windmill Hill Business Park, Whitehill Way, Swindon, Wiltshire SN5 6NX, UNITED KINGDOM  
 Company Registered in England and Wales No: 01771333 VAT Number: GB 813038069



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London Road, Shardlow  
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Telephone: 01332 793000  
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Entaco  
Unit 90 Heming Road  
Washford Ind Est  
Redditch  
Worcestershire B98 0EA  
FAO: Mr. S. Morris

Report No: E3323/62  
Issue No: 1  
Date: 02/12/2013

Order No: 008809

### STERILITY TEST REPORT

4 x AN 900ml PREM BN:029133

### STERILITY TEST DETAILS

Lab Ref No.:	60061211
Date of Receipt:	13/11/2013
Date of Test:	16/11/2013
Incubation Period:	14 Days
Method:	EP/USP MEMBRANE FILTRATION
Standard Test Method:	ILS 13.01

RESULT: PASS

#### COMMENTS

The above samples were sent to our sub-contracting laboratory Queens Medical Centre, QC Unit, F floor, West block, Nottingham University hospitals, Derby Road, Nottingham, NG7 2UH.

Suzanne Ashley BSc (Hons)  
Leading Technician