Unit 46, Heming Road, Washford Industrial Estate
Redditch, Worcestershire, B98 0EA UK
Telephone: 08450 739529 International: +44 (0)1527 830942
Fax: +44 (0) 1527 830949
Email: sales@redditchmedical.com
www.redditchmedical.com

Redditch Medical
Innovative thinking

CERTIFCATE OF CONFORMITY

PRODUCT:	Sterile Denatured Ethanol 70% v/v with WFI Quality Water
PRODUCT CODE:	DEWFI10-1LS
PRODUCT DESCRIPTION:	Low Residue, Rapid Action, Fast Drying, Alcohol Disinfectant
BATCH NUMBER:	031170
MANUFACTURING DATE:	Mar 2014
EXPIRY DATE:	Feb 2016
IRRADIATION NUMBER:	S11128432-1-1
IRRADIATION DOSE:	25kGy's to 45 kGy's
STERILITY TEST REF:	60061777
CERTIFICATE OF ANALYSIS No:	031170
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	Keith Hannan
POSITION	FACILITY OPERATOR
DATE	1ST APRIL 14

A division of Entaco Limited - a History of Excellence
Company Registration Number: 03322474 VAT Number: 687896737

Unit 46, Heming Road, Washford Industrial Estate
Redditch, Worcestershire, B98 0EA UK
Telephone: 08450 739529 International: +44 (0)1527 830942
Fax: +44 (0) 1527 830949
Email: sales@redditchmedical.com
www.redditchmedical.com

Redditch Medical
Innovative thinking

CERTIFCATE OF ANALYSIS

PRODUCT: Sterile Denatured Ethanol 70% v/v with WFI Quality Water

PRODUCT CODE: DEWFI10-1LS

PRODUCT DESCRIPTION: Low Residue, Rapid Action, Fast Drying, Alcohol Disinfectant

BATCH NUMBER: 031170

MANUFACTURING DATE: Mar 2014

EXPIRY DATE: Feb 2016

PRODUCT ASSESSMENT		
FILTRATION:	0.2 micron in line filter	PASS
COLOUR:	Clear	Pass
ODOUR:	Alcoholic	Pass
CLARITY:	Clear	Pass
SG:	0.880 – 0.888	Pass

APPROVAL	
APPROVED BY	Keith Harrow
POSITION	Facility Operator
DATE	1st April 14

synergyhealth
our work protects your world

http://www.synergyhealthplc.com

Certificate of Irradiation

Date Issued: 29-Mar-2014 UK32S11128432-1-1

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

Order Information

Account Number:	101254
Synergy Health Sales Part Reference:	1004283
Customer Reference Number:	8212
Product Description:	INSPEC IPA 1 LTRE TRIGGER 25-45KGY
Validation Reference:	4.1372
Quantity Received:	336
Customer Minimum Specification kGy:	25.0
Customer Maximum Specification kGy:	45.0
Customer Unit Lot/Batch Number:	6 PLTS; FRI 14.03.14; B/NO. 031170

Irradiation Data

Date and Time of Irradiation:	29-Mar-2014 01:50
Reference Dose Range kGy:	32.0 - 34.7
Calculated Minimum Dose kGy:	28.3
Calculated Maximum Dose kGy:	37.6

Irradiation Release Authorised By Synergy Health plc

ILS Limited
Shardlow Business Park
London Road, Shardlow
Derbyshire. DE72 2GD

Telephone: 01332 793000
Fax: 01332 799044
Website: www.ils-limited.co.uk

Report No: E3323/106
Issue No: 1
Date: 06/06/2014

Redditch Medical
Discovery 2, Netpark
William Armstrong Way
Sedgefield
TS21 3FH
FAO: Mr. K. Harrow

Order No: 9543

STERILITY TEST REPORT

2 x DE 1L PREMIUM BN:031170

STERILITY TEST DETAILS

Lab Ref No.:	60061777
Date of Receipt:	09/04/2014
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.

SMAshley

Suzanne Ashley BSc (Hons)
Leading Technician

Registered in England No. 3009343

ILS Limited
Shardlow Business Park
London Road, Shardlow
Derbyshire. DE72 2GD

Telephone: 01332 793000
Fax: 01332 799044
Website: www.ils-limited.co.uk

Report No: E3323/98
Issue No: 1
Date: 12/05/2014

Redditch Medical
Discovery 2, Netpark
William Armstrong Way
Sedgefield
TS21 3FH
FAO: Mr. K. Harrow

Order No: PO009543

TEST REPORT

LIMULUS AMOEBOCYTE LYSATE TEST

DE 1L PREMIUM BN:031170

Lab Ref No.: 66024493

Date of Receipt: 09/04/2014

Methodology: The methodology used was that as described in ILS 12.07 covering current EP & USP monographs.

RESULT: Pass <0.1 Eu/ml

COMMENTS
The above sample was tested according to the validated method detailed in Report No. E3323/15.

The above results were generated and reported in a GMP compliant laboratory.

Suzanne Ashley BSc (Hons)

Leading Technician

Registered in England No. 3009343