



Certificate of Analysis-TITANIUM WIPES--CRY/TTM/049

PRODUCT batch number: P731000

Product Name:	TITANIUM WIPES Working Solution	
Reference:	CRY/TTM/047	
This is to certify that TITANIUM WIPES Working Solution bearing the Batch No: P731000 were tested on 2017.10.11 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear pale yellow liquid free of matter	Conforms
ODOUR	Chlorine like	Conforms
ClO ₂ Concentration (ppm)	Conforms to QCF CRY/TTM/050	Conforms

Product Name:	TITANIUM WIPES Base Solution	
Reference:	CRY/TTM/045	
Date of Manufacture:	2017.10.11	
Date of Expiry:	2019.10	
This is to certify that TITANIUM Wipes Base Solution was tested on 2017-10-11 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear liquid free of matter	Conforms
SPECIFIC GRAVITY	1.000-1.010	1.006
pH	2.0 – 3.0	2.2
STERILITY	No growth	Conforms

DRF2550 CRY/TTM/049/Issue1





Product Name:	TITANIUM WIPES Activator Solution	
Reference:	CRY/TTM/046	
Date of Manufacture:	2017.10.03	
Date of Expiry:	2019.10	
This is to certify that TITANIUM WIPES Activator Solution was tested on 2017.10.03 and found to comply with all requirements as set out in the specifications and method of analysis.		
PROPERTIES	SPECIFICATION	RESULTS
APPEARANCE	Clear and free of matter	Conforms
pH	11.0-11.5	11.1
SODIUM CHLORITE	0.2% +/- 0.005%	0.198%
STERILITY	No growth	Conforms

Completed By:

Reviewed By:

Quality Department: E Andrews

S Kielinska

Date: 2018-01-04

Date: 2018-01-04



Certificate of Analysis

Sample Details

Product Name: Titanium burstable wipes

Batch Number: P731000

Batch Code: P731000

Job Number: 20137

Sample ID: 69485

Registered date: 20-Dec-17

Completion date: 04-Jan-18

Data

Test Method	Test	Specification	Result	Units	Pass/Fail
Direct Inoculation Sterility Test (cFTM)	DI Sterility (cFTM)	Complies / Does Not Comply	Complies	N/A	Pass
Direct Inoculation Sterility Test (TSB)	DI Sterility (TSB)	Complies / Does Not Comply	Complies	N/A	Pass
Membrane Filtration Sterility Test (cFTM)	MF Sterility (cFTM)	Complies / Does Not Comply	Complies	N/A	Pass
Membrane Filtration Sterility Test (TSB)	MF Sterility (TSB)	Complies / Does Not Comply	Complies	N/A	Pass

The product meets the following specification:

Sterility Test current Ph. Eur. by Membrane Filtration and Direct Inoculation. Validation report HVAL_R405.v1

LabHQ Product Specification Version: 1

Approval

Approved By: Katie Pearson

Approved Date: 04-Jan-2018 10:50:59

User ID: kpearson

Title: Laboratory Supervisor

This approval is performed by electronic signature in LabHQ LIMS and is the legal equivalent of the approver's hand-written signature.



<http://www.synergyhealthplc.com>

Certificate of Irradiation

Date Issued: 20-Nov-2017

UK31S12010101-1-1

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

EN ISO 11137-1:2015 Sterilisation of Health Care Products
 EN ISO 9001:2008 Quality Management System
 EN ISO 13485:2012 Quality System - Medical Devices

The Tristel Company Ltd
 Unit 4C Lynx Bus Park, Fordham Rd
 Newmarket
 Suffolk CB8 7NY
 UNITED KINGDOM

Order Information

Account Number:	100708
Synergy Health Sales Part Reference:	1103783
Customer Reference Number:	705989
Product Description:	BURST/TITANIUM WIPES 10-20KGY
Validation Reference:	1.6922
Quantity Received:	57
Customer Minimum Specification kGy:	10.0
Customer Maximum Specification kGy:	20.0
Customer Unit Lot/Batch Number:	P731000, 2 PALLETS.

Irradiation Data

Date and Time of Irradiation:	20-Nov-2017 15:56
Reference Dose Range kGy:	14.7 - 14.9
Calculated Minimum Dose kGy:	12.3
Calculated Maximum Dose kGy:	15.0

Irradiation Release Authorised By Synergy Health plc

Processing Site: Moray Road, Elgin Industrial Estate, Swindon, SN2 8XS Phone No: +44 (0)1793 601004

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