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Appendix R

Autoclave Registration Certification, Destruction Efficiency & Microbiological Testing Results

eurofins | ams

Accreditation No: 15773
Accredited for compliance with ISO/IEC 17025

TGA Licence No: MI - 15112007- LI - 002191 - 11

APVMA Licence No: 6139

Final Study Report

Sponsors

State Waste Services (NSW) Pty Ltd
Med-X Pty Ltd
9, Kenoma Place,
Arndell Park NSW 2148

Test Facility

Eurofins ams Laboratories Pty Ltd
8 Rachael Close
Silverwater NSW 2128

Author
Hong Liu, Dip

13th March 2018

Report Reference
1806570GLP

Eurofins | ams
A Eurofins BioPharma Product Testing Laboratory

ABN: 47 075 467 757

8 Rachael Close, Silverwater
NSW 2128, Australia

2/120 Bluestone Circuit, Seventeen Mile Rocks
QLD 4073, Australia

T | +61 2 9704 2300
www.amslabs.com.au

1.0 STUDY DIRECTORS STATEMENT

The study was conducted according to the procedures indicated by the sponsor. To the best of my knowledge and belief, the study was conducted to Client specifications, and there were no circumstances that may have changed the quality and integrity of the study without prior knowledge of client.

Signed ..... Date 16/03/18

Author
Hong Liu (Microbiologist, General Microbiology)

2.0 QUALITY ASSURANCE STATEMENT

The study was conducted in accordance with the OECD Principles on Good Laboratory Practice and ISO /IEC 17025.
I certify that the data contained in this report is a true and accurate record of the experimental results.

Signed ..... Date 16/03/18

Quality Assurance Unit

3.0 ANALYSTS STATEMENT

The work reported herein is a true and accurate account of the results obtained in carrying out the stated procedures.

Signed---------- Date----16/03/18----

Monali Shivalkar
(Microbiologist, General Microbiology)

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4.0 LABORATORY CREDENTIALS

Eurofins amsLaboratories is licensed by the Australian Therapeutic Goods Administration for microbiological analysis and testing (TGA Licence No. 15112007-LI-002191-11 and GMP Certificate No MI-2016-LI-10302-1) & the Australian Pesticide and Veterinary Medicines Authority (APVMA Licence No 6139). The laboratory is registered with the US Food and Drug Administration (DUNS No 754742088 and Facility Establishment Identifier No 3006635869) & NATA Accredited to ISO 17025 (Accreditation Number 15773). The premise is certified by Office of Gene Technology Regulator as a Physical Level 2 (PC2) facility (Certificate No 2649).

5.0 QUALITY ASSURANCE PROGRAMME

The Quality Assurance Unit of Eurofins amsLaboratories has inspected the data contained in this report, and also assisted in the preparation of this final report.

6.0 CONFIDENTIALITY

The data and contents of this report are held in confidence by Eurofins amsLaboratories Pty Limited. They will only be made available to the Sponsor and authorized government inspectors if requested. No further disclosures will be made without seeking and receiving the prior permission of the Sponsor in writing.

7.0 STORAGE OF RECORDS

All materials, methods, variations to this protocol and results are recorded on laboratory worksheets. These records will remain archived at Eurofins amsLaboratories for 5 years.

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STUDY REPORT

1.0 STUDY TITLE: Validate the claim of reducing the microbial contamination load by minimum of 4 logs using BONDTECH BTT6X13 located at 9, Kenoma Place, Arndell Park 2148

2.0 SPONSOR: Med-X Pty Ltd
9, Kenoma Place,
Arndell Park NSW 2148

3.0 TEST FACILITY: Eurofins ams Laboratories Pty Ltd, 8 Rachael Close, Silverwater NSW 2128

4.0 TEST SUBSTANCE IDENTIFICATION:

3 x 20BIs retrieved after autoclave operation of the maximum load capacity of the BONDTECH BTT6X13
6 Positive Control Count BIs transported to Med-X Pty Ltd and back to Eurofins ams Laboratories Pty Ltd
1 Positive Control without transporting to Med-X Pty Ltd

5.0 EXPERIMENTAL START DATE:

06th February, 2018

STUDY COMPLETION DATE:

15th February, 2018

6.0 STUDY OBJECTIVE:

To validate the claim of reducing the microbial contamination load by minimum of 4 logs using BONDTECH BTT6X13

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7.0 TEST METHOD:

TME-157 Biological Indicator (BI) Evaluation
TME-155 Spore Strip Counts

8.0 TEST SYSTEM/STRAINS:

Geobacillus stearothermophillus spores ATCC 7953

9.0 REFERENCES:

9.1 TGAL-A Survey of Biological Indicator Viable Counts-1991, by Shelley Tang and Dominic Phillips.
9.2 USP XXV.2008.<55> Biological Indicators-Resistance Performance Tests.
9.3 USP, Chapter 55
9.4 NASMSA Sportrol Product Insert
9.5 ISO 11138-1:2006 Sterilisation of Healthcare Products – Biological Indicators – Part 1: General Requirements
9.6 Microbiological Validation of BONDTECH Sterilisation Unit BTT6X13 protocol Document No: 17-TVP-037

10.0 INTRODUCTION:

60 Test BIs were retrieved after autoclave operation from 3 maximum loads and 3 Positive Control BIs were transported to Med-X Pty Ltd and back to Eurofins ams Laboratories Pty Ltd. They were subject to Growth/No Growth testing to validate reduction of the microbial contamination load by minimum of 4 logs using BONTECH BTT6X13. The 3 Positive Control BI's transported to Med-X Pty Ltd and back to Eurofins ams Laboratories Pty Ltd along with 1 Positive Control BI which was not transported to Med-X Pty Ltd were subject to enumeration test to ensure the count of minimum 10^5 Spores/BI.

11.0 STUDY MATERIALS:

11.1 MEDIA:

- Tryptone Soy Agar plates (TSA)
- Biological Indicators EZTest

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11.2 REAGENTS:

- 9mL Sterile Deionised Water (DIW)

11.3 EQUIPMENT:

- 55-60°C Incubator
- Pipettes
- Pipette tips
- Bio Safety Cabinet (BSC)
- Vortex
- Petri dishes
- Sterile forceps
- Sterile glass beads

12.0 TEST METHOD:

12.1 **Biological Indicators**

The evaluation organism was *Geobacillus stearothermophilus* (previously known as *Bacillus stearothermophilus*). The BI's were EZTest BI's in the form of self-contained vials. Each BI contained a minimum of $1.0x10^5$ spores/unit. The Certificate of Analysis from the manufacturer is attached in Appendix 2.

Materials and methods

12.2 **On Site**

12.2.1 The autoclave was initiated with a warm up cycle. Four 700L bins are required for a full load cycle.

12.2.2 Each of the four bins was filled to the maximum capacity with waste and BI's were wrapped in distinguishable cloth with autoclave tape and placed in the center of the bins in five locations: the four corners and the middle. The BI's from the cycle were retrieved and placed into an 'esky' for transportation back to the laboratory.

12.2.3 From the first cycle, only 2 of the 20 BI's were not retrieved. All other BI's from the three cycles were retrieved after autoclaving.

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12.2.4 The BI locations were labelled as follows: Cycle run number, bin number, and BI position number eg. Cycle 1, Bin1- L1.

12.2.5 Bin number 1 is the bin positioned into the autoclave first, BI locations 1,2,3,4 & 5 are top left, top right, bottom left, bottom right and centre respectively.

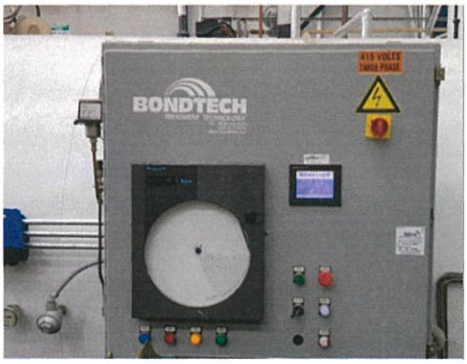

Figure 1: BONDTECH 6X13autoclave

Figure 2: Positions of the BI's

Figure 3: example of the wrapped BI's with autoclave tape

12.3 **Laboratory Procedures**

12.3.1 The autoclaved BI's were retrieved from each bin in each of the 3 cycles and transported with the control BI's to Eurofins ams in Silverwater.

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12.3.2 The self- contained BI's from the autoclave cycles were processed and incubated at 55-60°C for 2-7 days with visual checks in between. Three control BI's (not autoclaved) were also processed and incubated with the others as colour references.

12.3.3 The additional three control BI's which had not been autoclaved including the one BI which was not transferred to Med-X Pty Ltd were processed, heat shocked and serially diluted and plated in duplicate to ensure there were no significant loss in BI counts during transport (Table 3).

12.3.4 All plates were incubated at 55-60°C for 2 days. Plates were counted and averages determined.

13.0 STUDY RESULTS:

13.1 Table 1. BI Test Results post BONDTECH BTT6X13. Growth or No Growth of BI's

Description	Cycle 1 ref 1804084/1-20	Cycle 2 ref 1804085/1-20	Cycle 3 ref 1804086/1-20
Bin 1 – L1	No Growth	No Growth	No Growth
Bin 1 – L2	*	No Growth	No Growth
Bin 1 – L3	*	No Growth	No Growth
Bin 1 – L4	No Growth	No Growth	No Growth
Bin 1 – L5	No Growth	No Growth	No Growth
Bin 2 – L1	No Growth	No Growth	No Growth
Bin 2 – L2	No Growth	No Growth	No Growth
Bin 2 – L3	No Growth	No Growth	No Growth
Bin 2 – L4	No Growth	No Growth	No Growth
Bin 2 – L5	No Growth	No Growth	No Growth
Bin 3 – L1	No Growth	No Growth	No Growth
Bin 3 – L2	No Growth	No Growth	No Growth
Bin 3 – L3	No Growth	No Growth	No Growth
Bin 3 – L4	No Growth	No Growth	No Growth
Bin 3 – L5	No Growth	No Growth	No Growth
Bin 4 – L1	No Growth	No Growth	No Growth
Bin 4 – L2	No Growth	No Growth	No Growth
Bin 4 – L3	No Growth	No Growth	No Growth
Bin 4 – L4	No Growth	No Growth	No Growth
Bin 4 – L5	No Growth	No Growth	No Growth

* unable to retrieve BI's from the bin after autoclaving

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13.2 Table 2. Control BIs (not autoclaved) Results. Growth or No Growth of BI's

	Positive Control BI's ref 1804086/21	Positive Control BI's ref 1804086/22	Positive Control BI's ref 1804086/23
Growth/No Growth	Growth	Growth	Growth

13.3 Table 3. BI Control Population Confirmation (Average Count)

Inoculum as per manufacturer's certificate	Positive Control 1 Ref 1804088/1	Positive Control 2 Ref 1804088/2	Positive Control 3 Ref 1804088/3	Positive Control not transferred to Med-X Pty Ltd Ref 1804089
$2.0x10^5$ cfu/unit	$1.5x10^5$ cfu/unit	$3.2x10^5$ cfu/unit	$1.3x10^5$ cfu/unit	$3.2x10^5$ cfu/unit

14.0 STUDY CONCLUSION:

The study provides evidence that BONDTECH BTTX13 Waste Sterilizer machine met the sponsor confirmed performance criteria of four log ten reduction for autoclave sterilization using the destruction of biological indicators (BI) as the measure of success.

REPORT SUBMITTED BY:

Hong Liu (Microbiologist, General Microbiology)

16/03/18
Study Completion Date

Eurofins | ams
A Eurofins BioPharma Product Testing Laboratory

ABN: 47 075 467 757

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EZTest®

Biological Indicator

CERTIFICATE OF ANALYSIS

Reorder No: EZS/5

Geobacillus stearothermophilus 7953[1]

Biological Indicator for: Steam Sterilization.

Culture: **EZTest** Media, 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Purity: No evidence of contaminants using standard plate count techniques.

Lot No: **S-500** Manufacture Date: 2017 June 05

Expiration: 2019 June 05

Heat Shocked Population: 2.0×10^5 Spores / Unit

Carrier size: ¼" x ¾" (6 mm x 19 mm)

Assayed Resistance:

	D-Value[2]	Survival	Kill	
Steam 121°C	1.8	6.01[3]	16.91[3]	min
Steam 132°C	0.7	1.5[4]	5.0[4]	min
Steam 134°C	0.6	1.5[4]	5.0[4]	min
Steam 135°C	0.6	1.0[4]	5.0[4]	min

Z-value: 22.4°C

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

[1] Culture is traceable to a recognized culture collection identified in USP and ISO 11138.
[2] Resistance was determined in an AAMI BIER vessel and calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.
[3] Survival/Kill values are calculated according to a formula in USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation.
[4] Empirically derived data.

Certified By: _____ 20 June 2017

Quality Representative

Complete Quality Control testing results available upon request.

MesaLabs

Bozeman Manufacturing Facility
10 Evergreen Drive
Bozeman, MT 59715
T: 303/987-8000 ♦ F: 406/585-9219
www.mesalabs.com

EZTest®

Steam

Monitoring Frequency:

For optimum control of hospital sterilized goods, we recommend that EZTest biological indicators be used to monitor every sterilizer load. The JCHA and AAMI require a BI to monitor each sterilizer load containing implantable products. Monitoring use is the responsibility of each institution or end user.

Instructions for Use:

CAUTION: After sterilization, the contents of the EZTest biological indicator are hot and under pressure. Always allow to cool at least 10 minutes. Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.

NOTE: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

A. **Exposure:**
   1. Remove an appropriate number of EZTest units from the box.
   2. Identify the indicators by labeling pertinent process information.
   3. It is recommended that at least two BI's be used per cycle.
   4. Place the EZTest biological indicators in a horizontal position with representative materials to be sterilized. These materials should be located in the "worst case" (least lethal location) in the load.
   5. Select the appropriate cycle and process the load.
      NOTE: If an IUSS cycle is selected the goods should be unwrapped. If the come up time is less than one minute, a three minute exposure cycle may have to be extended to four minutes to ensure that the BI is killed.
   6. Remove from the sterilizer and allow to cool for at least 10 minutes.
   7. Retrieve the EZTest biological indicators from the test load.
   8. The chemical indicator on the label changes from blue to a green/gray color when exposed to steam. Extended exposure will result in further change to a black color. The purpose of the chemical indicator is to distinguish exposed from unexposed units. NOTE: a black color does not indicate acceptable sterilization.

B. **Incubation:**
   Any microbiological incubator that is adjusted for 55 to 60°C will satisfy the incubation conditions for the EZTest. To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

C. **Interpretation:**
   1. Examine the indicator at regular intervals for any color change (i.e. 8, 12, 18 and 24 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
   2. Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate hospital personnel (i.e. Infection Control). Always retest the sterilizer with several EZTest biological indicators throughout the test load. EZTest biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from Mesa Labs.
   3. The incubation time is 24 hours (meets the US FDA/RIT protocol).
   4. Record the results.
   5. Dispose of all used EZTest biological indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

D. **Use of Controls:**
   1. As a positive growth control, place an activated, un-sterilized EZTest biological indicator in each incubator on a daily basis.
   2. Examine the positive indicator at regular intervals (i.e. 4, 8, 12, 18 and 24 hours). The yellow color is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of as mentioned above.
   3. If the positive control does not grow, do not use the units from this box. Contact Mesa Labs.

E. **Storage:**
   1. Store EZTest biological indicators at room temperature. Do not desiccate.
   2. Do not store these indicators near sterilants or other chemicals.
   3. EZTest biological indicators have a shelf life which is clearly designated on each box. Rotate your stock accordingly.

   NOTE: Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

Rev.13
Part No.7193

Relevant certification

ATTACHMENT 3

CERTIFICATE OF PLANT DESIGN REGISTRATION

Occupational Health & Safety Act 2000
Occupational Health & Safety Regulation 2001

ABN: 77 682 742 966
Phone: (02) 4321 5498
Fax: (02) 4325 5094

Registration No: PV 6-153790/11 ABN: 70077391541 Issue Date: 22/11/2011

Controller: MEDIVAC TECHNOLOGY PTY LTD
Postal Address: PO BOX 656
BAULKHAM HILLS
NSW 1755

Plant Type: Pressure Vessel Original

Design Description:

Quality System	No
Hazard Level	C
Contents	Harmful
Chamber 1 Volume (l)	644
Chamber 1 Design Pressure (kPa)	-100 TO 350
Chamber 1 Temperature (°C)	148
Chamber 1 Fluid Type	Gas
Chamber 2 Volume (l)	21
Chamber 2 Design Pressure (kPa)	400
Chamber 2 Temperature (°C)	152
Chamber 2 Fluid Type	Gas
Drawing Number & Revisions	001.0000.00000 REV C
Pressure Vessel	Other
Other Type	STEAM JACKETED PRESSURE VESSEL

CONDITIONS:

1. This registration applies only to the design described above which has been notified to WorkCover NSW in accordance with the OHS Regulation 2001.
2. The plant owner will require a copy of this certificate. A copy of this certificate must therefore be supplied to the manufacturer so that it can, in turn be provided to the supplier and owner with the item of plant or equipment.
3. WorkCover NSW reserves the right to audit the registered design at any time to assess compliance with its Acts and Regulations. If an audit is undertaken, detailed information may be requested relating to the design of the plant. Design systems of work and documentation may also be audited. If an audit identifies non-compliance, all plant built to that design may require modifications, and in some cases, may be prohibited from use.
4. This Registration is automatically invalidated if the design is altered to an extent that requires new measures to control risks. A person must not use, or cause or allow plant manufactured to the original design to be used at a workplace unless notification of the alteration, or the prescribed form, has been confirmed by WorkCover NSW.
5. The Registration Number should be quoted in all correspondence to WorkCover regarding this item. Any queries should be addressed to WorkCover's Licensing Unit.

Fee Paid: $ 130.00 Receipt No: 09-2317

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CERTIFICATE OF PLANT DESIGN REGISTRATION

Occupational Health & Safety Act 2000
Occupational Health & Safety Regulation 2001

ABN: 77 682 742 966
Phone: (02) 4321 5488
Fax: (02) 4325 5094

Registration No: BOIL 6-153791/11 ABN: 70077391541 Issue Date: 17/11/2011

Controller: MEDIVAC TECHNOLOGY PTY LTD
Postal Address: PO BOX 856
BAULKHAM HILLS
NSW 1755

Plant Type: Boiler Alteration

Design Description:

Hazard Level	B
Design Pressure (kPa)	1400
Volume (l)	78
Temperature (Co)	199
Drawing Number and Revisions	102.0601.00000 REV A
Boiler Type	Electric
The Boiler Produces?	Steam

CONDITIONS:

1. This registration applies only to the design described above which has been notified to WorkCover NSW in accordance with the OHS Regulation 2001.
2. The plant owner will require a copy of this certificate. A copy of the certificate must therefore be supplied to the manufacturer as that item, in turn, be provided to the supplier and owner with the item of plant or equipment.
3. WorkCover NSW reserves the right to audit the registered design at any time to assess compliance with its Acts and Regulations. If an audit is undertaken, detailed information may be requested relating to the design of the plant. Design systems of work and documentation may also be audited. If an audit identifies non-compliance, all plant built to that design may require modifications, and in some cases, may be prohibited from use.
4. This Registration is automatically invalidated if the design is altered to an extent that requires new measures to control risks. A person must not use, or cause or allow plant manufactured to the original design to be used at a workplace unless notification of the alteration, or the prescribed form, has been confirmed by WorkCover NSW.
5. The Registration Number should be quoted in all correspondence to WorkCover regarding this item. Any queries should be addressed to WorkCover's Licensing Unit.

Fee Paid: $ 130.00 Receipt No: 09-2317

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NSW HEALTH

ENVIRONMENTAL HEALTH BRANCH

Mr Paul McPherson
Executive Chairman
Medivac Technology Pty Ltd
Unit 8, Lot 1B Kleins Road
NORTHMEAD NSW 2152

Ref: 03/9864

Dear Mr McPherson

NSW HEALTH APPROVAL OF MEDIVAC TECHNOLOGY CLINICAL WASTE TREATMENT DEVICE

I write in response to your email request for documentation of the approval of the 'Medivac Metamizer ML' with your current address details listed above.

This is to confirm that NSW Health issued an approval of the MediVac Technology Clinical Waste Treatment Device on 8 August 2002.

This letter of approval states that the *"MediVac Technology clinical waste treatment device which utilizes steam sterilization and a grinding process to reduce the bacterial and viral loads and spore loads of treated waste to levels of log 6 and log 4 respectively has been approved by the A/Director-General of NSW Health Department. The approval is for the treatment of certain types of clinical waste subject to conditions set out in schedule 1".*

In addition a letter was issued by NSW Health on 29 October 2004 advising that the Medivac MetaMizer ML is considered to be a *"new model to extend to the range of clinical waste treatment devices manufactured by MediVac because it uses the same technology and therefore comes under the existing approval granted by the Director-General on 15 July 2002".*

I hope this information is satisfactory.

Should you require any additional information in regard to the MediVac clinical waste treatment device approvals, please contact Ms Anne Ford A/Manager General Environmental Health on Tel (02) 9816 0225 or Email anne.ford@doh.health.nsw.gov.au

Yours sincerely

Professor Wayne Smith
Director Environmental Health Branch
27 November 2008

NSW Department of Health
ABN: 92 697 899 630
PO Box 798 Gladesville NSW 1675
Building 31, Gladesville Hospital
Victoria Road, Gladesville NSW 2111
Telephone (02) 9816 0234 Fax (02) 9816 0240
Website www.health.nsw.gov.au

Tab 33

NSW HEALTH
DEPARTMENT

ENVIRONMENTAL HEALTH BRANCH

OUR FILE: 02/3864

Mark Butler
Managing Director
Medivac Technology Pty Ltd
PO Box 478
CASTLE HILL NSW 2154

Dear Mr Butler

NSW HEALTH APPROVAL OF MEDIVAC TECHNOLOGY CLINICAL WASTE TREATMENT DEVICE

Reference is made to your application for approval of the Medivac Technology clinical waste treatment device.

The Medivac Technology clinical waste treatment device which utilizes steam sterilization and a grinding process to reduce the bacterial and viral loads, and spore loads of treated waste to levels of log 6 and log 4 respectively has been approved by the A/Director-General of NSW Health Department. The approval is for the treatment of certain types of clinical waste subject to the conditions set out in Schedule 1.

The treated waste will need to be reclassified in accordance with EPA requirements before it can be disposed to landfill.

New systems or technologies that vary to this approval will need to be re-submitted for consideration.

If you would like to discus the approval please contact Nicole Badger on 98160225 or email nbadg@doh.health.nsw.gov.au

Yours faithfully,

Neil Shaw
Manager, General Environmental Health

PO Box 798, Gladesville NSW 1675
Administration Building, Gladesville Hospital
Victoria Road, Gladesville NSW 2111
Telephone (02) 9816 0373 Fax (02) 9816 0377

STUDY DIRECTOR:	**SPONSOR:**
Name: Minal Patel	Name: Chris Liney
Position: Team Leader, General Microbiology, Eurofins ams Laboratories	Position: Managing Director Med-X Pty Ltd
Signature:	Signature:
Date: 04/01/2018	Date: 04/01/18

Function	**Name**	**Signature**	**Date of Agreement**
Study Director:	Minal Patel		04/01/2018
Sponsor/Study Monitor:	Med-X Pty Ltd		
Analyst/s:	Hong Liu		04/01/18
Quality Assurance Manager:	Fergus O'Connell		

LABORATORY TEST FACILITY

Eurofins ams Laboratories Pty Ltd
8 Rachael Close
Silverwater NSW 2128
AUSTRALIA

STUDY TIMETABLE

Study Initiation Date: 02/01/2018
Proposed Experimental Initiation Date: 02/01/2018
Proposed Experimental Completion date: 10/01/2018
Proposed Final Report Date: 12/01/2018

1.0 INTRODUCTION

1.1 Objective and scope

The aim of this study was to validate the claim of reducing the microbial contamination load by minimum of 4 logs using BONDTECH BTT6X13 located at 9, Kenoma Place, Arndell Park 2148.

Geobacillus stearothermophilus ATCC 7953 spores (EZTest Biological indicator) will be used for the study as they are recognised as the most resistant form of micro-organism to chemical and physical sterilisation. *Geobacillus stearothermophilus* has therefore been chosen owing to the fact that it is an obligate thermophile whose spore is one of the most heat-resistant spores of aerobic microorganisms. The genus *Geobacillus* has a growth-temperature range of 37-75°C, with an optimum at 55-65°C.

1.2 Regulatory Acceptance

The study is designed in accordance with accepted principles of experimental investigation.

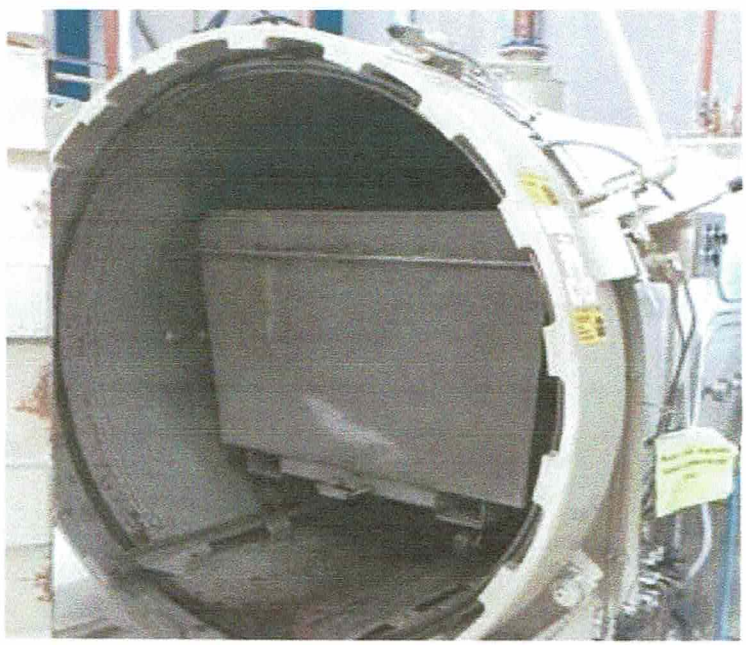
1.3 Laboratory Practice

This study will be conducted in accordance with the OECD Principles of Good Laboratory Practice (1998).

2.0 STUDY DETAILS

2.1 Test item

2.1.1 BONDTECH BTT6X13- Refer to Appendix 3 for the specifications and details of the autoclave.



2.2 Materials and Equipment

2.2.1 Pipettes
2.2.2 Pipette tips
2.2.3 Petri dishes
2.2.4 Biological indicators EZTest
2.2.5 Bio Safety Cabinet (BSC)
2.2.6 Tryptone Soy Agar (TSA)
2.2.7 55-60°C Incubator
2.2.8 9mL Sterile Deionised Water
2.2.9 Vortex

3.0 METHOD

3.1 Autoclave operation at Med-X Pty Ltd

3.1.1 The study will be carried out in triplicate.

3.1.2 The maximum load capacity of the BONDTECH BTT6X13 is 4 x 700L bins. The study will be carried out at the maximum load capacity of the autoclave.

3.1.3 Five BIs will be placed inside each full loaded bin (total 20 BIs) for each run. One BI in every corner of the bin and one will be placed in the centre of the bin.

3.1.4 At the end of the run, all 20 BIs will be retrieved and transported back to Eurofins ams Laboratories for further testing.

3.1.5 Total six Positive Control Count BIs will be transported to Med-X Pty Ltd along with the other BIs. The positive control BIs will not be subjected to any treatment and will be transported back to Eurofins ams Laboratories to perform the enumeration to ensure the count of minimum 10^4 Spores/BI. Transporting the Positive Control BI to Med-X Pty Ltd and back to Eurofins ams Laboratories will be carried out prior to performing the enumeration to ensure the spore viability during the transit of BIs.

3.2 BI testing at Eurofins ams Laboratories

3.2.1 Three Positive control BIs which will be transported to Med-X Pty Ltd and back to Eurofins ams Laboratories will be subjected to enumeration test at Eurofins ams Laboratories, which will include the serial dilution and plating of the suspension. TSA will be poured in to the plates and plates will be incubated at 55-60^{0}C for 2 Days. The colonies will be enumerated at the end of the incubation period.

The other three Positive control BIs which will be transported to Med-X Pty Ltd and back to Eurofins ams Laboratories will be subjected to Growth/No Growth analysis along with the Test BIs.

One Positive Control Count will be carried out at Eurofins ams Laboratories without transporting the BI to Med-X Pty Ltd.

3.2.2 The Test BIs will be subjected to Growth/No Growth testing and will be incubated at 55-60^{0}C for 2-7 Days. Three Positive Control BIs will be incubated along with the

BIs. At the end of the incubation period the BIs will be examined for any colour change.

4.0 QUALITY ASSURANCE

Process Audit required which will be scheduled during the study. The Eurofins ams Laboratories Quality Assurance Unit is responsible for reviewing Study Plans, the final report and monitoring critical phases, processes, facilities, and personnel on a regular basis as well as auditing official reports to ensure that they accurately and completely reflect the raw data and comply with GLP. Audits are performed in accordance with relevant Test Facility Standard Operating Procedures.

5.0 PROTOCOL AMENDMENTS AND DEVIATIONS

5.1 The Study Director may make written amendments or deviations to this protocol. All amendments and deviations will be signed and dated by the Study Director, Quality Assurance, the Test Facility Manager and when necessary by the Sponsor's Representative.

5.2 All amendments and deviations will be signed at the time the change is made and stored with the protocol.

5.3 Any deviation and/or amendment to the Study Plan will be reported in the Final Report.

5.4 The impact of the amendment on the study will be described.

5.5 Amendments must be reviewed by QA. Copies of any amendments and deviations will be sent to the sponsor during the course of the study. A Deviation Log is provided in Appendix 2.

6.0 REPORTING

The Final Report will include - but will be not limited to - the following information:

6.1 Name and address of the Sponsor and of the Test Facility

6.2 Compliance with Good Laboratory Practice

6.3 Statement of Study Director

6.4 Statement of Quality Assurance

6.5 Identification of the study (title, code, key personnel)

6.6 Period of the study (Study initiation, approval of study plan, start of experimental phase, end of experimental phase, date of Final Report)

7.0 ARCHIVING

The original data, documentation, Study Plan and final report will be archived in the GLP archive of Eurofins ams Laboratories, Silverwater, in accordance with Eurofins ams SOP No QA-004 'Control of Quality Documentation'.

8.0 STATISTICS

Statistical methods used during the course of the study will be documented in the study file and summarised in the report.

9.0 DISTRIBUTION LIST

One copy of the signed study plan will be distributed to the following study participants:

9.1 Study Director
9.2 Sponsor/Study Monitor
9.3 Facility Manager
9.4 Quality Assurance Manager

10.0 ACCEPTANCE CRITERIA

10.1 The positive Control count for all three BIs should be minimum 10^4 Spores/BI.
10.2 For all the Test BIs, there should be No growth detected (No colour change in the Self-contained BI) at the end of the incubation period.

APPENDIX 1

RESPONSIBILITIES

- The General Microbiology Department and QA Departments are responsible for the overall adherence to the protocol. Specific duties will include the following:
- Facilitating the timely execution of this protocol by provision of appropriately trained personnel, equipment and materials as required.
- Ensuring compliance with GLP, in house SOP's, and this Protocol.
- Ensuring that the testing equipment to be used is adequately maintained and all monitoring/controlling instruments are calibrated, as appropriate.
- Each step of the process as defined in this protocol must pass the defined acceptance criteria.
- All employees shall be trained for their responsibilities in executing the validation protocol.
- This validation study protocol must be approved by all signatories prior to execution.
- Med-X Pty Ltd to review and approve the protocol.

APPENDIX 2

DEVIATION LOG

The following log sheet is to be filled out in the event that any deviations occurred in this protocol. For each deviation enter the Test Number or activity where the deviation was found, a description of that deviation and whether it was critical or non-critical (C or N respectively).

Sheet ____ of ____

Test Number or Activity	Deviation	C or N	Initials/Date

APPENDIX 3

PROPOSAL FOR:

MEDICAL WASTE AUTOCLAVE SYSTEM

BY:
BONDTECH CORPORATION

PROPOSAL INCLUDES:
THE MANUFACTURING/PROCUREMENT, TESTING OF
AUTOCLAVE STERILIZATION EQUIPMENT

May 1, 2012 R1
April 28, 2012

1.1.0 BONDTECH AUTOCLAVE/STERILIZER SYSTEM SPECIFICATIONS

High vacuum/High pressure, Computer controlled, Bondtech autoclave system to treat biomedical waste on-site

1.1.1 AUTOCLAVE DIMENSIONS AND CAPACITY

BTT6X13
6' dia X 13' long
Pressure Grade Carbon Steel
Number of bins: 3 or 4/per load
Capacity: ~ 500 to 600 kg/cycle (@ standard Med Waste density of 5.5 lb/cuft)
~ 750 to 850 kg/cycle (Port Waste)

1.1.2 AUTOCLAVE VESSEL SPECIFICATIONS

Opening Assembly: Single door/quick opening door/safety pin interlock
Loading Arrangement: Horizontal
Pressure Vent: Spray condenser

1.1.3 INSULATION

The exterior of the autoclave will be insulated with 2" of fiberglass, which will be covered with an aluminum jacket to protect the insulation, and to make sure the equipment can be kept clean.

1.1.4 PROCESS VALVES

Complete with the process valves including steam supply, pressure vent and safety relief.
The steam inlet valve is a ***high-resolution pneumatic proportional valve for a smooth accurate control of steam pressure***. For safety, the steam inlet valve is a normally closed valve that closes in the event of any power loss.

1.1.5 AUTOCLAVE VESSEL DESIGN

The autoclave vessel is designed, fabricated, tested and certified in accordance with the ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, for Unfired Pressure Vessels. The vessel is designed for full vacuum. The sterilization unit is formed and welded into a horizontal cylindrical pressure vessel with a hydraulic quick opening door. The vessel includes two rigid support saddles to facilitate a simple installation. The front face of the
vessel has a machine groove for the rigid high temperature seal gasket.

1.1.6 VACUUM SYSTEM.

Vacuum: Vacuum: 24-28" Hg.
High Efficiency Vacuum System

Vacuum Capability: 24"-28" Hg, 3 minutes

Pre-vacuum: The pre-vacuum process will evacuate the autoclave 24"-28" Hg. This process will achieve the removal of air from the autoclave to provide a quick and efficient penetration of steam throughout the medical waste load.

Post-vacuum: The post-vacuum process removes excess steam from the vessel and expedites the steam purging process. This process removes excess moisture from waste load resulting in a lighter/drier treated waste product for disposal. Moisture removal effectively controls nuisance odors.

1.1.7 STEAM CONDENSER

Independent steam condenser manufactured of pressure-grade steel. The condenser is designed for quick and efficient steam purge from the autoclave vessel. Process steam is fully condensed externally to the autoclave vessel. ***Steam purge process is completed within approx 2-3 minutes.***

1.1.8 DOOR OPERATION, SEALING AND LOCKING MECHANISM

The door is hinged mounted on the autoclave. Mounting arrangements to provide full movement to a full open position. Preferred sealing system to utilize one-piece extruded material O-ring seal type. The door has a positive lock type safety design per the ASME requirements. The locking mechanism is interlocked with the control system to prevent opening the door while under pressure, and to prevent pressurization when the door is unlocked. The door is designed with several safety features that include electric/mechanical interlock switch, PLC interlock, door safety handle interlock, visual site gauge for pressure monitor and analog dial pressure/temperature indicators.

1.1.9 MATERIAL HANDLING

Autoclave tracks will be provided for the autoclave bins.
Optional automatic hydraulic Lift Table for assisting in loading/unloading bins

1.1.10 SYSTEM PIPING.

The autoclave system will completely piped at the factory prior to shipment for simple installation. The system piping will consist of the following:

- Steam condenser piping – steam outlet piping direct to steam condenser. Steam is condensed by controlling water flow through the steam condenser with respect to steam pressure inside the vessel. The water flow control minimizes the consumption of water.
- Condensate Drains Steam traps (2) – front and rear steam traps maintains the vessel free of condensate.
- Vacuum Valve/Piping – autoclave is hard piped to either steam ejector or vacuum pump for integrating vacuum system to vessel.
- Steam Inlet Valve/Strainer – proportionally controlled steam inlet valve for smooth and accurate control of steam pressure inlet. Steam inlet valve is controlled by a PID loop controlled by the PLC.

1.1.11 CONTROL SYSTEM/PROCESS VALVES/CONTROL PANEL & INSTRUMENTATION

The autoclave control panel is package in a NEMA 12 rated panel. The autoclave system is controlled by a state-of-the-art "SuperMicro" Programmable Logic Controller (PLC) with modem hookup capabilities for online support. The PLC performs automatic sterilization control control that includes *pre-vacuum, pressurization/heat soak, vent and post-vacuum. The PLC monitors pressure vessel* conditions for providing safety interlock for door operation.

1.1.12.1 SUPERMICRO PROGRAMMABLE LOGIC CONTROLLER (PLC).

The FX2N Series PLC provides the function controls that automatically commands the process cycle steps for the autoclave system. Extensive data memory (over 8,000 Data Registers) for capturing real time operating parameters that continuously monitors autoclave system performance.

The FX2N Series PLC support on-line troubleshooting/programming functions, used in system development and commissioning. Remote programming/monitoring capability by modem provides for immediate technician support. This PLC system has the external data link integration capability for communication with other peripheral systems (PC, network, control systems, etc).

Powerful features include:

- Windows Programming - Use Ladder, List or SFC languages.
- Operator Interfaces – Flexible selection to match specific customer application
- Extensive Program Memory – 8,000/16,000 steps
- Extensive Data Memory – 8000 Data Registers
- Enhanced Program Throughput – 80 nanoseconds/step
- Enhanced Process Control – Auto-Tuning, PID loop
- High-Speed Processing–60KHz counters, 10ms timed&50us hardware interrupts
- Embedded Motion Control – 20,000 hz pulse train, Trapezoidal ramp instructions
- High Function Math – 32 bit floating point, Square Root, Trigonometry
- Year 2000 Compliant – Y2K Compliant, 4 digit year
- Real Time Clock/Date – For scheduling date and time stamping
- Flexible Configurations – From 16 to 256 I/O & extensive special function I/O capabilities
- Communications – Built-in 2nd port (RS-232/RS422/RS485) & PLC-PLC networking
- Open Network Connectivity – Modules for Profibus DP, Profibus DP I/O, AS-I & CC Link

1.1.12.2 SYSTEM PROGRAMMING

PLC program application is based on the industry standard ladder logic. Programming can be performed by authorized personnel with access to system entry code.

Simple pushbutton entry pad allows the authorized personnel to enter specific parameters including the following:

- Pre-Vacuum Set Point
- Pre-Vacuum Timer
- Sterilization Temperature/Pressure
- Sterilization Heat Soak Time
- Vent Time Set Control
- Post-Vacuum Set Point
- Post-Vacuum Timer

In addition to the above, specific alarms are setup for triggering equipment shutdown and notifying the operator in the event that temperature and/or pressure parameters are not satisfied.

The startup program will be installed and tested by Bondtech technicians during startup.

1.1.13 CONTROL SYSTEM PRINTER - Honeywell Circular Chart Recorder

The control system printer is a state of the art Honeywell printer. The printer generates continuous data that provides the history of every autoclave cycle.

The Honeywell 4500 series printer will record and generate chart data that includes the following:

- Time and Date of every autoclave cycle.
- Cycle Start and Cycle End Time.
- Continuous Cycle Vacuum & Pressure
- Continuous Cycle Temperature

2.0 BONDTECH SHREDDING SYSTEM . HIGH VOLUME

Feed Material - General Autoclaved Medical Waste composed of plastic films, plastics containers, plastic tubing, cloth, glass, light gage steel medical sharps (scalpels, scissors, syringes etc)

Feed Method - By bin tipper. Materials delivered by Bondtech Autoclave Bin

Discharge Method - To customer supplied compactor or collection container

Throughput Rate - **BTT/MM-70 - shredder rated to accept 3000 lbs. per hour**

Shred Size - Approx. 1" wide x 4" to 8" lengths.

2.1 BTT/MM-70E SHREDDER

Cutting Chamber - 29" x 52"
- Two hexagonal, counter rotating shafts (5.2")

Knives - Shaft center distance: 9-7/16"
- Number of knives: 48 - Approx

- Knife width: 1.5" (39 mm)
- Knife diameter: 14.4"
- **# of teeth per knife: Two, offset hex for quick materials capture**
- Knife material: Heat-treated alloy steel
- Contoured cleaning fingers and hex bore spacers between knives

Drive System - **60HP, 3 phase**
- Planetary Gear Reducer

Fast/Slow Shaft Speed - **21 / 17 rpm**

Maximum Tooth Force - **54,600 lbs.**

Maximum Torque - **32,700 ft-lbs.**

SEAL SYSTEM - **Special Configured for Medical Waste**

2.2 SUPPORT STAND
- 6" wide flange construction
- 60" discharge height
- Designed to clear customer's compactor/discharge container

2.3 BTT/MM-70E FEED ASSIST HYDRAULIC RAM HOPPER
- A-36 Plate - Reinforced plate construction
- Ram opening 33" x 66" approx.
- **Hydraulic cylinder** clevis mounted to heavy-duty ram platen
- Guide Mechanism – Guide Rollers

2.4 CONTROL PANEL
- NEMA 4 enclosure/Keyed power switch
- Illuminated function buttons for shredder operation
- Circuit Breaker w/lockable door operating mech.
- Full Voltage, across-the-line, magnetic motor starters
- Control power transformer – 24 VDC
- Allen Bradley Programmable logic controller-system op.& monitoring
- Run time hour meter/Emergency Stop Button

2.5 HYDRAULIC CART TIPPER . NO TIPPER
TIPPING WILL BE PERFORMED BY FORK LIFT SYST