PLA-TIR-E-2021-M002-00

TEST·INSPECTION REPORT

Biocompatibility Test

Manufacturer Name: Plasmapp Co., Ltd.

Representative: Youbong, LIM

Location: BVC-111, 125, Gwahak-ro, Yuseong-gu, Daejeon 34141, Republic of Korea

Product Name: Low temperature plasma sterilizer and sterilant

Brand Name: STERLINK™ and STERMATE™

Model Name: STERLINK mini and STERLOAD™ mini

Serial/Lot Number: M072BWF009A and SM21J006

Test·Inspection Item: Biocompatibility Test

Testing Laboratory:

Korea Testing and Research Institute
98, Gyoyukwon-ro, Gwacheon-si, Gyeonggi-do 13810, Republic of Korea

Decision: Pass

Plasmapp Research Institute

Biocompatibility Test

1. Test schedule

1.1 Date of test beginning: 16 Nov. 2021

1.2 Date of test completion: 27 Dec. 2021

2. Test article

Low temperature plasma sterilizer (STERLINK mini, S/N: M072BWF009A)

Sterilant (STERLOAD™ mini, Lot No.: SM21J006)

3. Test guideline

3.1 The tests were performed according to the ISO 10993-5 standard in compliance with the principles of Good Laboratory Practice (GLP).

3.2 Information of testing materials

3.2.1 Coupons

Material	**Dimensions [W × L × T, mm]**
Aluminum (Al 5052)	20 × 50 × 1
Aluminum (Al 6061)	20 × 50 × 2
Stainless steel (SUS 316L)	20 × 50 × 1
Stainless steel (SUS 304)	20 × 50 × 1
Titanium	20 × 50 × 1
High density polyethylene (HDPE)	20 × 50 × 1
Polypropylene (PP)	20 × 50 × 2
Polytetrafluoroethylene (PTFE)	20 × 50 × 1

3.2.2 Sterilant

Brand	STERMATE™
Model	STERLOAD™ mini
Lot Number	SM21J006
Expiration date	Sep. 2022
Manufacturer	Plasmapp Co., Ltd.
Comments	Sterilant cassette for STERLINK mini

3.2.3 Measuring instrument

Equipment	Manufacturer	Model	Internal S/N	Calibration date
High temperature data logger	MADGETECH	HiTemp140	PO-C-036	02 Sep. 2021
Pressure data logger	MADGETECH	PR140	PQ-C-035	10 Feb. 2021

3.3 Test methods

In order to confirm the biological safety of the sterilized objects by STERLINK mini, after full cycle of chamber mode, the cytotoxicity test was performed for the sterilized various material coupons. **For the worst-case condition, the coupons were sterilized in three consecutive full cycle of chamber mode.** The temperature and pressure during the sterilization process were measured.

4. Test results*

4.1 Results of biocompatibility test

The results of cytotoxicity test, the eight types of samples sterilized by three consecutive full cycle of chamber mode were grade 2 or lower, and it was determined that cytotoxicity was not observed according to the ISO-10993-5. (A grade higher than grade 2 is considered cytotoxic)
The cytotoxicity test results for sterilized each material coupon were attached as a test report with the following name.

Material	Test results	Test report
Aluminum (Al 5052)	Grade 1	MC_Al5052
Aluminum (Al 6061)	Grade 1	MC_Al 6061
Stainless steel (SS 316L)	Grade 0	MC_SS316L
Stainless steel (SS 304)	Grade 0	MC_SS304
Titanium	Grade 0	MC_Ti
High density polyethylene (HDPE)	Grade 1	MC_HDPE
Polypropylene (PP)	Grade 1	MC_PP
Polytetrafluoroethylene (PTFE)	Grade 0	MC_PTFE

*The time evolution of pressures and temperature inside the chamber during the sterilization process were described in the Appendix 1.

4.2. Pressure parameter data during sterilization process [Torr]

Cycle number	1st sterilant injection		2nd sterilant injection		Purification
	Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Base[a] (< 3 Torr)	Diffusion[b] (20 - 100 Torr)	Final base[c] (< 3 Torr)
1	0.50	41.7	1.60	46.8	1.60
2	0.50	41.6	0.98	45.7	1.09
3	0.19	45.6	1.09	46.3	1.60

4.3. Temperature parameter data during sterilization process [ºC]

Cycle number	Sterilization phase 1			Sterilization phase 2		
	Load[d] (40-60ºC)	Chamber[e] (55-60ºC)	Vaporizer[f] (110-130ºC)	Load[d] (40-60ºC)	Chamber[e] (55-60ºC)	Vaporizer[f] (110-130ºC)
1	45.4 – 57.2	55.7 – 58.2	117 – 122	48.2 – 58.9	56.8 – 58.4	114 – 121
2	44.9 – 55.3	56.1 – 58.7	121 – 127	47.0 – 57.5	57.9 – 59.1	122– 127
3	45.2 – 55.7	55.9 – 57.9	116 - 123	47.5 – 56.9	55.9 – 58.1	118 - 124

4.4. Time parameter data during sterilization process [s]

Cycle number	Sterilization phase 1 (300 ± 1 s)	Sterilization phase 2 (300 ± 1 s)
1	300	300
2	300	300
3	300	300

5. Conclusions

(1) The result of the cytotoxicity test, all test samples were evaluated grade 2 or lower under the ISO 10993-5 standard despite being exposed to three consecutive full cycle sterilization. It means that the tested materials are not cytotoxic after sterilization.

(2) According to the test results, the residues on the eight material coupons after sterilized with chamber mode of STERLINK mini was not affected to viable cells.

[a]The base pressure just before injection of the sterilant.
[b]The diffusion pressure after diffusion of the sterilant which is complete.
[c]The base pressure after injection and purification.
[d]The load temperature is measured by the temperature data logger described in 3.2.3.
[e]The chamber temperature is controlled by K-type thermocouple.
[f]The vaporizer temperature is controlled by K-type thermocouple.

Appendix 1

1. Pressure and temperature curves of the biocompatibility test

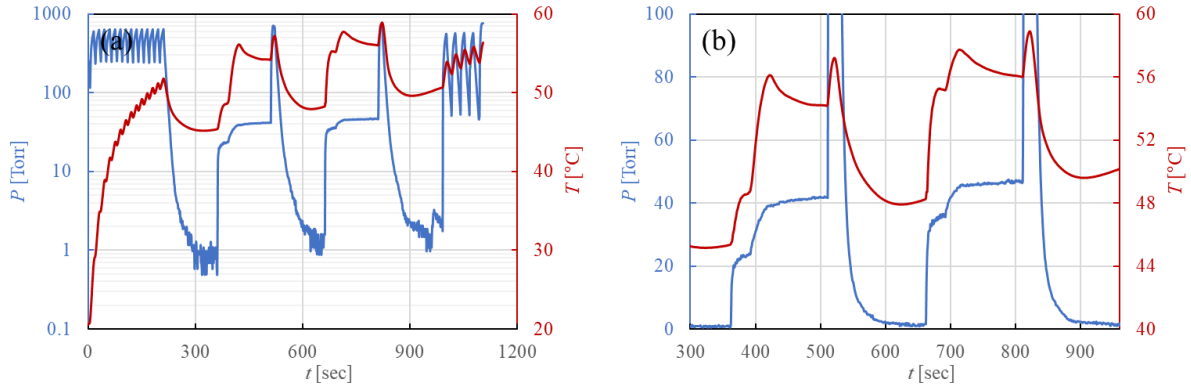

Figure 1.1 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 1st full cycle of test.

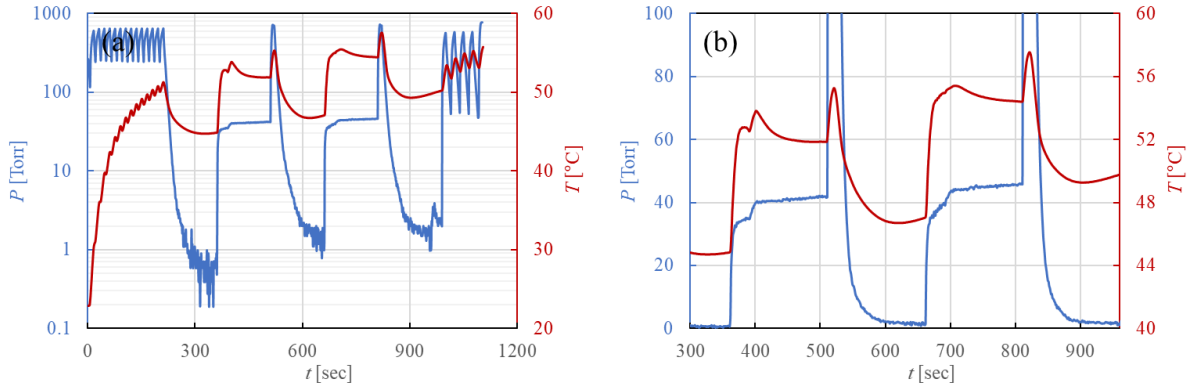

Figure 1.2 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 2nd full cycle of test.

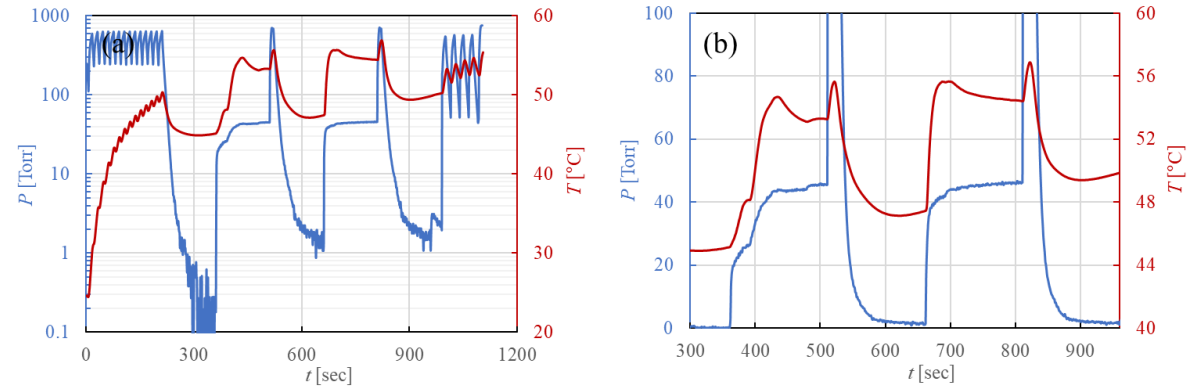

Figure 1.3 (a) The whole plot of pressure and temperature curve during the full cycle and (b) magnified plot of diffusion phase for 3rd full cycle of test.