

STERIKING® Tyvek® Pouches and Rolls
Performance Qualification Testing in V-PRO™ 1 Low Temperature Sterilizer,
completed on 26/7-27/7/2011 at Hämeenlinna Central Hospital

Objective

Verification of the STERIKING® Tyvek® packaging material's suitability to STERIS V-Pro 1 Vaporized Hydrogen Peroxide Sterilization System.

Efficacy of the STERIS V-Pro 1 Hydrogen Peroxide Sterilization can be confirmed by successful completion of three consecutive cycles containing STERIKING® Tyvek® packages with chemical and biological indicators.

After exposure, the process indicator must demonstrate the required color change and the biological indicator must show no growth to verify proper vaporized hydrogen peroxide penetration.

Test equipment

- STERIS V-PRO™ 1 Low Temperature Sterilizer (S/N 0315309-22)
- STERIS Verify® VH2O2 Process Indicator (REF PCC036, LOT 019382, expiry date 08/2011)
- STERRAD® Cycle Sure® 24 Biological Indicator (Bacillus stearothermophilus, ATCC 7953, REF 14324, LOT 335107, expiry date 02/2012)
- STERIKING® Tyvek® pouches (REF LTSS5A, LOT 0902)

Methodology

One biological indicator and one process indicator were placed into a LTSS pouch. The pouch was closed and placed into another LTSS pouch. The outer pouch was closed accordingly. Identical double pouched Tyvek® packages with indicators inside were prepared. Two of the packages were placed on the top and two on the lower shelf in V-Pro 1 chamber.

A full, four phase sterilization cycle was run. At the end of the cycle all the packages were removed and the indicators were recovered. Required process indicator color change was confirmed (from both internally placed and readily printed on the packaging material).

The same procedure was repeated for three consecutive cycles.

All cycles passed and retrieved biological tests have shown no growth.

Copies of the cycle records are attached.

CONCLUSIONS

The performance qualification testing for STERIKING® Tyvek® packaging has been successful verifying the suitability of the material to STERIS V-Pro 1 Vaporized Hydrogen Peroxide Sterilization System.

Sincerely,

Hanna-Kaisa Kyyrönen
Clinical Specialist
Health Care Products
Wipak Oy

Appendix 1. Process Parameters of the three consecutive cycles

KAMMIO AVATTU: 11:55:35

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= VALMIS TYHJENNYSKESN =

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TULOSTEEN TARKASTAJA:

KOKONAISJAKSO = 0:55:35

ILMAUS = 0:07:57

STERILOINTI = 0:41:52

VALMISTELU = 0:05:46

KUORMA 072601

Z	11:31:53	50,3	747,8
A	11:31:13	50,3	0,1
A	11:25:13	50,4	0,9
S	11:23:56	50,6	490,7
S	11:21:56	49,9	503,3
S	11:21:43	49,8	10,5
S	11:15:43	49,8	6,5
S	11:15:40	49,8	0,4
S	11:15:16	49,9	0,4
S	11:12:50	50,5	495,2
S	11:10:50	49,8	507,2
S	11:10:37	49,8	10,4
S	11:04:37	49,9	5,4
S	11:04:34	49,9	0,4
S	11:04:11	50,1	0,4
S	11:01:40	50,1	497,6
S	10:59:40	50,0	509,1
S	10:59:28	50,1	12,0
S	10:53:28	50,3	6,5
S	10:53:24	50,3	0,4
S	10:53:01	50,4	0,4
S	10:50:47	49,8	495,7
S	10:48:47	50,1	507,8
S	10:48:34	50,2	9,9
S	10:42:34	50,4	5,4
S	10:42:31	50,4	0,4
S	10:42:11	50,4	0,3
C	10:42:04	50,4	0,4
C	10:41:34	50,2	0,3
C	10:40:18	49,7	7,2
C	10:40:18	49,7	0,2
C	10:37:18	50,3	3,9
C	10:36:35	50,1	748,5

- Aika L=C P=Torr

HUOMAUTUKSET:-----

KUORMAN TUNNUS: *Load 1*

KAYTTAJAN TUNNUS:-----

VHP VANHENTUU 060712

VHP ERÄNRO. HC0661P7

SARJA # 0315309-22

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STERILOINTILAITE VHP

JAKSOJEN MÄÄRÄ 620

PVM, 26-07-11

JAKSON ALKUAIKA10:36:18

==== VHP -JAKSO ===

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KAMMIO AVATTU: 13:59:19

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= VALMIS TYHJENNYSKESN =

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TULOSTEEN TARKASTAJA:

KOKONAISJAKSO = 0:56:14

ILMAUS = 0:08:01

STERILOINTI = 0:42:21

VALMISTELU = 0:05:52

KUORMA 072603

Z	13:59:02	50,2	747,6
A	13:58:22	50,2	0,1
A	13:52:22	50,1	0,9
S	13:51:01	50,3	493,3
S	13:49:01	49,9	500,4
S	13:48:48	50,0	10,6
S	13:42:48	49,9	6,4
S	13:42:45	49,9	0,4
S	13:42:22	50,0	0,4
S	13:39:49	50,7	492,3
S	13:37:49	50,4	507,9
S	13:37:36	50,4	10,5
S	13:31:36	50,5	6,3
S	13:31:33	50,5	0,4
S	13:31:10	50,4	0,4
S	13:28:34	50,1	492,9
S	13:26:34	50,4	508,7
S	13:26:21	50,4	10,6
S	13:20:21	50,3	6,4
S	13:20:18	50,3	0,4
S	13:19:55	50,4	0,4
S	13:17:22	49,9	493,4
S	13:15:22	50,1	508,3
S	13:15:10	50,1	10,1
S	13:09:10	50,1	6,4
S	13:09:06	50,2	0,4
S	13:08:47	50,3	0,3
C	13:08:40	50,3	0,4
C	13:08:10	50,4	0,3
C	13:06:53	50,6	7,1
C	13:06:53	50,6	0,1
C	13:03:53	49,8	3,9
C	13:03:05	50,1	759,4

- Aika L=C P=Torr

HUOMAUTUKSET:-----

KUORMAN TUNNUS: *Load 3*

KAYTTAJAN TUNNUS:-----

VHP VANHENTUU 060712

VHP ERÄNRO. HC0661P7

SARJA # 0315309-22

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STERILOINTILAITE VHP

JAKSOJEN MÄÄRÄ 622

PVM, 26-07-11

JAKSON ALKUAIKA13:02:48

==== VHP -JAKSO ===

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