

Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

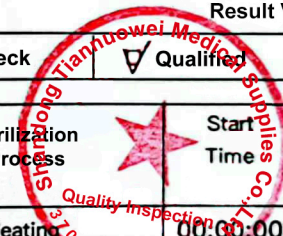
Furnace No: Sterilizer: Sterilization Batch: 20230913-100 Date: 23/09/13 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Ssniderm PU ROLL	0341161409	10.2InX8yd	340	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	0.0	Max:	0.0	45.0	60.0	Fail
Preconditioning Humidity(%RH)	--	Min:	0.0	Max:	0.0	35.0	90.0	Pass
Preconditioning Time	--	0.0				10.0	90.0	Fail
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		0.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.0				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.0	0.0	To	0.0	0.0	3.0	Fail
Pressure change at end of EO injection(kPa)	80.0	34	-24.8	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	51.1	Max:	51.7	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	76.1	Max:	77.7	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	00:00:00	00:00:00	00:00:00
Precondition	00:00:00	00:00:00	00:00:00
Pre-vacuum	00:00:00	00:00:00	00:00:00
Leak test	00:00:00	00:00:00	00:00:00
Steam injection	00:00:00	00:00:00	00:00:00
EO Injection	17:35:05	17:50:42	00:15:37
EO dwell	21:40:42	05:40:46	08:00:04
EO Removal	05:40:48	05:50:42	00:09:54
Air washing	06:09:06	06:50:50	00:41:44
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20230918-103 Date: 23/09/18 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU ROLL	0341161409	10.2inX2yd	500	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	52.2	Max:	52.2	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	41.2	Max:	41.2	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.3				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.6	-49.7	To	-49.2	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	59	-49.2	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	50.4	Max:	51.1	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	71.5	Max:	76.0	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	18:02:13	18:02:16	00:00:03
Precondition	18:02:13	18:02:17	00:00:04
Pre-vacuum	18:02:17	18:10:08	00:07:51
Leak test	18:10:08	18:15:11	00:05:03
Steam injection	18:15:11	18:16:14	00:01:03
EO Injection	18:16:14	18:34:42	00:18:28
EO dwell	21:34:44	05:34:46	08:00:02
EO Removal	05:34:48	05:45:22	00:10:34
Air washing	06:04:07	06:46:47	00:42:40
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

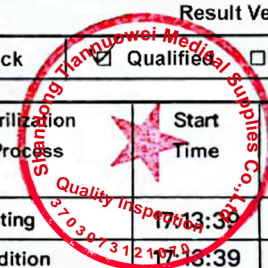
Furnace No: Sterilizer: Sterilization Batch: 20230912-99 Date: 23/09/12 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU ROLL	0341161409	8InX8yd	400	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	52.0	Max:	52.1	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	44.6	Max:	44.7	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.3				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.5	-49.7	To	-49.2	0.0	3.0	Fail
Pressure change at end of EO injection(kPa)	80.0	59	-49.2	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	50.9	Max:	51.5	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	74.6	Max:	76.3	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	17:13:39	17:13:42	00:00:03
Precondition	17:13:39	17:13:43	00:00:04
Pre-vacuum	17:13:43	17:21:35	00:07:52
Leak test	17:21:35	17:26:39	00:05:04
Steam injection	17:26:39	17:27:42	00:01:03
EO Injection	17:27:42	17:49:12	00:21:30
EO dwell	21:39:14	05:39:17	08:00:03
EO Removal	05:39:20	05:49:22	00:10:02
Air washing	06:07:52	06:49:51	00:41:59
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20230901-97 Date: 23/09/01 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU ROLL	0341161419	4inX8yd	106	
Sanuderm PU ROLL	0341161409	6inX8yd	180	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	52.7	Max:	52.7	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	42.0	Max:	42.0	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.2				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.5	-49.7	To	-49.2	0.0	3.0	Fail
Pressure change at end of EO injection(kPa)	80.0	59	-49.2	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	50.7	Max:	51.5	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	71.4	Max:	74.5	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	17:04:20	17:04:21	00:00:01
Precondition	17:04:20	17:04:22	00:00:02
Pre-vacuum	17:04:22	17:12:16	00:07:54
Leak test	17:12:16	17:17:18	00:05:02
Steam injection	17:17:18	17:18:21	00:01:03
EO Injection	17:18:21	17:53:51	00:35:30
EO dwell	22:03:52	06:03:54	08:00:02
EO Removal	06:03:56	06:14:04	00:10:08
Air washing	06:32:49	07:15:38	00:42:49
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20230907-98 Date: 23/09/07 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU dressing	0341161409	6InX8In	145	
Saniderm PU dressing	0341161409	4InX4In	150	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	52.1	Max:	52.2	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	43.4	Max:	43.4	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.3				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.6	-49.7	To	-49.1	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	59	-49.1	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	50.7	Max:	51.1	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	71.7	Max:	73.3	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	17:18:55	17:18:58	00:00:03
Precondition	17:18:55	17:18:59	00:00:04
Pre-vacuum	17:18:59	17:26:48	00:07:49
Leak test	17:26:48	17:31:52	00:05:04
Steam injection	17:31:52	17:32:55	00:01:03
EO Injection	17:32:55	18:14:30	00:41:35
EO dwell	22:04:30	06:04:33	08:00:03
EO Removal	06:04:37	06:13:48	00:09:11
Air washing	06:32:18	07:14:51	00:42:33
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20230915-102 Date: 23/09/15 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU ROLL	0341161409	10.2inX2yd	440	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	52.6	Max:	52.7	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	33.1	Max:	33.2	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.2				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.5	-49.8	To	-49.3	0.0	3.0	Fail
Pressure change at end of EO injection(kPa)	80.0	59	-49.3	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	50.9	Max:	51.6	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	65.7	Max:	68.0	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	17:35:13	17:35:15	00:00:02
Precondition	17:35:13	17:35:16	00:00:03
Pre-vacuum	17:35:16	17:42:54	00:07:38
Leak test	17:42:54	17:47:57	00:05:03
Steam injection	17:47:57	17:49:00	00:01:03
EO Injection	17:49:00	18:16:36	00:27:36
EO dwell	22:06:36	06:06:39	08:00:03
EO Removal	06:06:42	06:15:32	00:08:50
Air washing	06:34:00	07:15:59	00:41:59
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

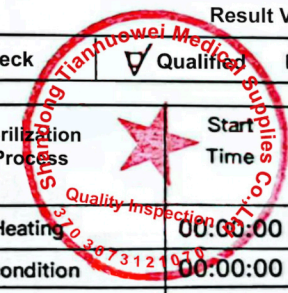
Furnace No: Sterilizer: Sterilization Batch: 20230919-104 Date: 23/09/19 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU roll	0341161409	10.2inX2yd	500	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified <input type="checkbox"/>

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	0.0	Max:	0.0	45.0	60.0	Fail
Preconditioning Humidity(%RH)	--	Min:	0.0	Max:	0.0	35.0	90.0	Pass
Preconditioning Time	--	0.0				10.0	90.0	Fail
Vaccum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.0				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.5	-49.8	To	-49.3	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	59	-49.3	To	10.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	51.4	Max:	51.9	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	45.0	Min:	64.3	Max:	66.9	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	5.0	5.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	00:00:00	00:00:00	00:00:00
Precondition	00:00:00	00:00:00	00:00:00
Pre-vacuum	00:00:00	00:00:00	00:00:00
Leak test	17:46:15	17:48:49	00:02:34
Steam injection	17:48:49	17:49:52	00:01:03
EO Injection	17:49:52	18:24:22	00:34:30
EO dwell	21:24:24	05:24:27	08:00:03
EO Removal	05:39:44	05:39:46	00:00:02
Air washing	05:51:48	06:34:05	00:42:17
flushing	00:00:00	00:00:00	00:00:00



Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20230806-99 Date: 23/08/06 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU roll	0341161409	10.2X2yd roll	234	

Production confirmation	
Doser:	
Operator:	
Supervisor:	
Quality control confirmation	
Inspector:	
Manager:	
Result Verification	
Check <input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified	



Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min		Max		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	51.5	Max:	51.5	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	52.0	Max:	52.0	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vacuum value(kPa)		-50.0				-60.0	59.0	Fail
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leak test(kPa)	--	0.3				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.6	-49.7	To	-49.0	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	61.1	-49.0	To	12.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	52.2	Max:	54.0	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	55.0	Min:	71.2	Max:	74.0	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	4.0	4.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	19:40:34	19:40:36	00:00:02
Precondition	19:40:34	19:40:36	00:00:02
Pre-vacuum	19:40:36	19:50:11	00:09:35
Leak test	19:50:11	19:55:15	00:05:04
Steam injection	19:55:15	19:57:18	00:02:03
EO Injection	19:57:18	20:50:09	00:52:51
EO dwell	21:05:09	05:05:13	08:00:04
EO Removal	05:05:15	05:17:26	00:12:11
Air washing	05:39:09	06:14:49	00:35:40
flushing	00:00:00	00:00:00	00:00:00

Shandong Tiannuwei Medical Supplies Co.,Ltd

Ethylene Oxide Sterilization Process Record

Furnace No: Sterilizer: Sterilization Batch: 20231107-154 Date: 23/11/07 Order: 1

Article Name	Lot No	Specification	CTN/	Quantity
Saniderm PU dressing	0842161409	8inX10in	360	
Saniderm PU dressing	0842161409	4inX4in	200	

Production Confirmation	
Doser:	
Operator:	
Supervisor:	
Quality Control Confirmation	
Inspector:	
Manager:	
Result Verification	
Check	<input checked="" type="checkbox"/> Qualified <input type="checkbox"/> Unqualified

Process Parameters	Setting Value	Actual Value				Requirement		Pass/Fail
		Min:		Max:		Min	Max	
Preconditioning Temperature(°C)	50.0	Min:	50.2	Max:	50.2	45.0	60.0	Pass
Preconditioning Humidity(%RH)	--	Min:	30.6	Max:	30.7	35.0	90.0	Pass
Preconditioning Time	--	15.0				10.0	90.0	Pass
Vaccum value(kPa)		-50.0				-60.0	59.0	Pass
Leak test time(Min)		5.0				1	10	Pass
Pressure change at end of leal test(kPa)	--	0.2				0.0	3.0	Pass
Pressure change at end of steam injection(kPa)	1.5	0.6	-49.8	To	-49.2	0.0	3.0	Pass
Pressure change at end of EO injection(kPa)	80.0	61.3	-49.2	To	12.1	0.0	150.0	Pass
EO weight injection(Kg)		0.0				0.0	130.0	Pass
Temperature(T1) during EO exposure(°C)	50.0	Min:	52.5	Max:	53.5	45.0	60.0	Pass
Humidity(RH) during EO exposure(%RH)	55.0	Min:	60.0	Max:	66.5	0.0	99.0	Pass
Pressure(P1) during EO exposure(kPa)	-50.0	Min:	0.0	Max:	0.0	--	--	Pass
EO dwell(Min)	480.0	480.0				478	482	Pass
Numbers of air washes	3.0	3.0				1	5	Pass

Sterilization Process	Start Time	End Time	Time elapsed
Heating	10:13:56	10:13:58	00:00:02
Precondition	10:13:56	10:13:59	00:00:03
Pre-vacuum	10:13:59	10:22:26	00:08:27
Leak test	10:22:26	10:27:29	00:05:03
Steam injection	10:27:29	10:29:31	00:02:02
EO Injection	10:29:31	10:57:43	00:28:12
EO dwell	11:07:43	19:07:47	08:00:04
EO Removal	19:07:51	19:19:39	00:11:48
Air washing	19:36:27	19:52:30	00:16:03
flushing	00:00:00	00:00:00	00:00:00

