

Environmental Protection 03/0379

Lawton Chiles Governor

Twin Towers Office Building 2600 Blair Stone Road Tallahassee, Florida 32399-2400

Virginia B. Wetherell Secretary

October 3, 1996

Mr. Jerry Bussell Vice President Operations Xomed Surgical Products 6743 Southpoint Drive N. Jacksonville, Florida 32216

Dear Dr. Bussell:

The Department has received the Title V General Permit Notification Form for the ethylene oxide sterilizers facility that you submitted on September 17, 1996.

Please note that in November of each year the Department will be mailing fee notices to those facilities using the Title V general permit. This annual operation fee is \$50 and it is due and payable between January 15 and March 1 of each year the facility is in operation and is subject to the requirements of the Title V general permit.

If you have or expect to have any changes in your mailing address, location address, responsible official, or phone number, please notify the Department at the following address:

Title V General Permits Office Bureau of Air Monitoring and Mobile Sources MS 5510 Department of Environmental Protection 2600 Blair Stone Road Tallahassee, Fl 32399-2400

If there are any changes in the facility status, including change of operating parameters or equipment, or if you have any additional questions regarding the Title V General Permit Program, please contact the District or local air program compliance inspector in your area.

Sincerely,

Dotty Diltz, Chief

Bureau of Air Monitoring and Mobile Sources

/DD

Ms. Lori Tilley, Duval County cc:

Zovsed

Ethylene Oxide Sterilization Facility Notification

Facility Name and Location

1. Facility Owner/Company Name (Name of corporation, agency, or individual owner): **Xomed Surgical Products** 2. Site Name (For example, plant name or number): Xomed Surgical Products 3. Hazardous Waste Generator Identification Number: 4. Facility Location: Street Address: 6743 Southpoint Drive N. 32216 City: Jacksonville County: Duval Zip Code:

Responsible Official

6. Name and Title of Responsible Official: Jerry Bussell, Vice President Operations 7. Responsible Official Mailing Address: Organization/Firm: Xomed Surgical Products 6743 Southpoint Drive N. Street Address: Zip Code: 32216 City: Jacksonville County: Duval 8. Responsible Official Telephone Number: Fax: (904) 279-7-587 Telephone: (904) 296-9600

Facility Contact (If different from Responsible Official)

9. Name and Title of Facility Contact (For example, plant manager): Marie Garnes, Director Technical Services 10. Facility Contact Address: Street Address: 6743 Southpoint Drive N. Zip Code: 32216 City: County: Duval Jacksonville 11. Facility Contact Telephone Number: Telephone: (904) 296-9600 Fax: (904) 279-7-587

DEP Form No. 62-213.900(3) Effective: 6-25-96

Facility Information

1(a). Provide the information below for each machine at the facility. Indicate the type of machine, the date of its purchase, and the date the control device was installed, if applicable.

		Date	Date	1	Date	Date		Date	Date
		Machine	Control	1	Machine	Control		Machine	Control
		Initially	Device		Initially	Device		Initially	Device
Type of Machine	aı l	Purchased	Installed	110	Purchased	Installed	ID	Purchased	Installed
Type of Machine	110	i urchasee	Ilistaticu	110	1 dichased	mazired		i di ciiasco	IIDMIIQ
Example	#1	03-OCT-93	03-OCT-93	#2	01-MAR-94	08-DEC-94	#3	03-JAN-95	
Sterilization Chamber				-					
Joslyn		Aug 91	01 Nov 9	91	<u> </u>				
Chamber Exhaust	-	,							
Jos1yn		Aug 91	01 Nov 9	1					
Aeration Room									
Joslyn		Aug 91	Ol Nov 9	1				· · · · · · · · · · · · · · · · · · ·	
2.(a) What was the total									
(b) If less than 12 mon Check why it is le			New owner	:: <u> </u>] New facil	lity: []			
(b) If less than 12 mon Check why it is le 3. What control technolo (Indicate with an "X".	ess than	12 months:	New owner Did not kee e added to m	: Lec	ords: []	o this genera			
(b) If less than 12 mon Check why it is le 3. What control technolo (Indicate with an "X". Acid-water scru	ess than ogy is r	12 months:	New owner Did not kee the added to re	: ep rec	ords: [] es pursuant t	o this genera			
(b) If less than 12 mon Check why it is le b. What control technology (Indicate with an "X". Acid-water scru Catalytic oxidate	ess than ogy is r) N bber ion uni	equired to be	New owner Did not kee the added to re	ep rec	ords: [] es pursuant t	·			
(b) If less than 12 mon Check why it is le 3. What control technolo (Indicate with an "X". Acid-water scru	ess than ogy is r bber ion unit	equired to be	New owner Did not kee oe added to re for vect No	ep rec	es pursuant t	o this genera	Del	ip	

DEP Form No. 62-213.900(3)

Page 12 of 13

Effective: 6-25-96

Equipment Monitoring and Recordkeeping Information

Check all log	s which are required to be kept on-site in accordan	ce with the requirements of this general permit:
(a) Purchase i	receipts for ethylene oxide purchases	<u> </u>
(b) Temperate	ure monitoring for oxidizer units	LAT. BA
(c) Liquor tan	k level monitoring	(*) 570 (*) 670 (*) 670
(d) Concentra	tions of ethylene glycol in scrubber systems	TK 15/10
(e) Exhaust co	oncentrations of ethylene oxide	[<u>X</u>]
(f) Performan	ce testing	<u> </u>
(g) Instrument	calibration	[<u>X</u>]
	Surrender of Existing Air	Permit(s)
Please indicate	e with an "X" the appropriate selection:	
	I hereby surrender all existing air permits author facility indicated in this notification form; specif	
[x]	No air permits currently exist for the operation of this notification form.	of the facility indicated in
	Responsible Official Cert	ification
addressed inquiry, th comply wit	ersigned, am the responsible official, as defined in in this notification. I hereby certify, based on infact the statements made in this notification are true th all terms and conditions of this general permit an apply notify the Department of any changes to the infact.	ormation and belief formed after reasonable a, accurate and complete. Further, I agree to as set forth in Part II of this notification form.
Signature	Jerry Aussell	Date

DEP Form No. 62-213.900(3)

Essective: 6-25-96

Ethylene Oxide Sterilization Facility Notification

Facility Name and Location

Facility Owner/Company Name (Name of corporation, agency, or individual owner):

Xomed Surgical Products

2. Site Name (For example, plant name or number):

Xomed Surgical Products

Hazardous Waste Generator Identification Number:

4. Facility Location:

Street Address:

6743 Southpoint Drive N.

City: Jacksonville

County: Duval

Zip Code:

32216

Facility Identification Number (DEP Use):

0310379

Responsible Official

6. Name and Title of Responsible Official:

Jerry Bussell, Vice President Operations

7. Responsible Official Mailing Address:

Organization/Firm:

Xomed Surgical Products

Street Address: City: Jacksonville

6743 Southpoint Drive N. County: Duval

Zip Code: 32216

8. Responsible Official Telephone Number:

Telephone:

(904) 296-9600

Fax: (904) 279-7-587

Facility Contact (If different from Responsible Official)

9. Name and Title of Facility Contact (For example, plant manager):

Marie Garnes, Director Technical Services

10. Facility Contact Address:

Street Address:

6743 Southpoint Drive N.

City:

Jacksonville

County: Duval

Zip Code: 32216

11. Facility Contact Telephone Number:

Telephone:

(904) 296–9600

Fax: (904) 279-7-587

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AUG 3 0 1996

Bureau of Air Monitoring & Mobile Sources

DEP Form No. 62-213.900(3) Effective: 6-25-96

Page 11 of 13

Facility Information

1(a). Provide the information below for each machine at the facility. Indicate the type of machine, the date of its purchase, and the date the control device was installed, if applicable.

Type of Machine	ID	Machine Initially Purchased	Date Control Device Installed	ID	Date Machine Initially Purchased	Date Control Device Installed	ID	Date Machine Initially Purchased	Date Control Device Installed
Example	#1	1	03-OCT-93	#2	01-MAR-94	08-DEC-94	#3	03-JAN-95	
Sterilization Chamber		in the second second		4.15	*	· · · · · · · · · · · · · · · · · · ·			-
Joslyn		Aug 91	01 Nov 9	1					
	+						,		
Chamber Exhaust				<u> </u>					
Joslyn		Aug 91	01 Nov 9	1					
			<u> </u>	<u> </u>					
Aeration Room				<u>ا</u>	**************************************		5		<u>.</u>
Joslyn		Aug 91	01 Nov 9						
	↓				_				
(a) What was the total(b) If less than 12 mor Check why it is less	nths, h	ow many? [_	months	: :: [lity: []	[0 , '	5] tons	
3. What control technological (Indicate with an "X"		required to b	e added to m	iachii	nes pursuant	to this genera	al per	mit?	
Acid-water scru	bber		Ot	her		[]	Ì		
Catalytic oxidat	ion un	it []	No	one re	equired	[]]		
Thermal oxidat	on un	it []							
Note: Unit consi acquisition, vacu system, steam gen recovery module,	um p erat	umping mo	odule, he ilant tra	at o	ezchanger er statio	system, n, water	cir chi	culation ller, wa	blower ter heate

DEP Form No. 62-213.900(3)

Effective: 6-25-96

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Gow gas sampling system. All areas are monitored by a HNV system which is an ETD monitoring system. All equipment was purchased from Joslyn Sterilizer Corporation, 5815 Country Road 41, Farmington, NY 14425. (Phone 1-716-398-2680).

Equipment Monitoring and Recordkeeping Information

Check all logs which are required to be kept on-site in accordance with the requ	irements of this general permit:				
(a) Purchase receipts for ethylene oxide purchases	[<u>X</u>]				
(b) Temperature monitoring for oxidizer units					
(c) Liquor tank level monitoring					
(d) Concentrations of ethylene glycol in scrubber systems					
(e) Exhaust concentrations of ethylene oxide	<u> </u>				
(f) Performance testing	[X]				
(g) Instrument calibration	X_				
Surrender of Existing Air Permit(s)					
Please indicate with an "X" the appropriate selection:					
I hereby surrender all existing air permits authorizing operation of the facility indicated in this notification form; specifically, permit number(s)					
No air permits currently exist for the operation of the facility indicated in this notification form.					
Responsible Official Certification					
I, the undersigned, am the responsible official, as defined in Rule 62-210.200, F.A.C., of the facility addressed in this notification. I hereby certify, based on information and belief formed after reasonable inquiry, that the statements made in this notification are true, accurate and complete. Further, I agree to comply with all terms and conditions of this general permit as set forth in Part II of this notification form. I will promptly notify the Department of any changes to the information contained in this notification.					
Signature Verry Bussell Aug Date	ust 28, 1996				

DEP Form No. 62-213.900(3) Effective: 6-25-96



UNITED STATES ENVIRONMENTAL PROTECTION AGENCE ECEIVED

ATLANTA FEDERAL CENTER 61 FORSYTH STREET ATLANTA, GEORGIA 30303-8960

MAR 0 6 2003

DIVEDON OF AIR RESOURCES MANAGEMENT

FEB 2 7 2003

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<u>CERTIFIED MAIL</u> RETURN RECEIPT REQUESTED

Jerry Bussell, VP Operations Medtronics XOMED 6743 Southpoint Drive North Jacksonville, FL 32216-0980 RECEIVED XC: SANDY B

MAR 10 2003 "FYI" Jim P

Bureau of Air Monitoring To ev
& Mobile Sources TRINA

Dear Mr. Bussell:

The purpose of this letter is to apprise you of the Environmental Protection Agency's (EPA) findings and evaluation of Medtronics XOMED (XOMED) compliance status following a compliance inspection of the ethylene oxide sterilizer facility on February 21, 2002. During the compliance inspection Mr. Floyd Ledbetter, the inspector, discovered that your facility was calculating your usage of ethylene oxide as the amount that is purchased and consumed by the facility versus that which is recycled. Our interpretation of 40 CFR Subpart O (Ethylene Oxide Emissions Standards for Sterilization Facilities) is that usage, as used in Subpart O Section 63.360(a), means the throughput amount of ethylene oxide in the sterilization chamber during all sterilizations, and not just that which was purchased and consumed.

In email correspondence of March 1, 2002, with EPA, XOMED stated that it placed 25.2 pounds of ethylene oxide in the sterilization chamber,152 times in 2001. This constitutes 3,830 pounds in a one year period. This is clearly greater than the 1,000 pound amount specified in Subpart O Section 63.360, and therefore makes XOMED subject to all requirements for sources using more than 1000 pounds of ethylene oxide. These requirements include the provisions of Subpart O Sections 63.360 thru 63.367 regarding General Provisions, Compliance and Performance Testing, Monitoring Requirements, Test Methods and Procedures, Reporting Requirements, and Recordkeeping Requirements.

EPA acknowledges that Subpart O does not directly address how to calculate the amount used when sterilization gas is recycled. However, based on the language and purpose of the regulations, EPA believes that an interpretation based on the throughput of sterilization gas through the sterilization chamber, rather than an interpretation based on the amount of gas consumed by the system, is most appropriate. EPA's determination is based on the fact that the language of the regulations suggests that the focus of the calculation is on the throughput of sterilization gas in the sterilization chamber. The definition of sterilization operation ("...any time when ethylene oxide is removed from the sterilization chamber through the sterilization

chamber vent...") indicates that the focus of the regulation is throughput. Similarly, the definition of sterilization chamber vent focuses on "...evacuation of ethylene oxide from the sterilization chamber...". Thus, applicability focuses on the use of the equipment, not on the source of the sterilization gas. Consistent with this view, the control requirements at Section 360.362 define controls in terms of emission reductions at the chamber vent, not after other downstream equipment. Nothing in the language of Subpart O suggests that applicability should consider recycling by relying only on the amount of ethylene oxide purchased to replace lost gas or other concepts that incorporate the concept of controls.

EPA is requesting that the facility meet all the applicable requirements of Subpart O not later than 180 days from receipt of this correspondence. Your permit issued by the Florida Department of Environmental Protection is written with maximum flexibility, and it is our understanding it will not need to be modified for compliance with the additional Subpart O requirements.

Your attention to this matter is appreciated. If you have questions or comments in applying this regulation, please call Mr. Floyd Ledbetter at 404-562-9218.

Sincerely,

Beverly H. Banister

Director

Air, Pesticides, and Toxics Management Division

cc: Howard L. Rhodes, FDEP James L. Manning, JRESD

UNITED STATES ENVIRONMENTAL PROTECTION AGE

REGION 4 ATLANTA FEDERAL CENTER 61 FORSYTH STREET ATLANTA, GEORGIA 30303-8980

MAR 0.6 2003

DIVISION OF AIR RESOURCES MANAGEMENT

13/0379-002

FFB 2 7 2003

4APT-AEEB

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Jerry Bussell, VP Operations Medtronics XOMED 6743 Southpoint Drive North Jacksonville, FL 32216-0980

Dear Mr. Bussell:

RECEIVED XC: SANDY B

MAR 1 0 2003 " = 4 I Bureau of Air Monitorine

& Mobile Sources

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Sincerely,

Beverly H. Banister

Director

Air, Pesticides, and Toxics Management Division

cc: Howard L. Rhodes, FDEP James L. Manning, JRESD



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AUG 4 1997

Bureau of Air Monitoring & Mobile Sources

July 31, 1997

Dotty Diltz, Chief
Bureau of Air Monitoring and Mobile Sources
Department of Environmental Protection
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32399-2400

DEO #0310379

Ref: Your memorandum of July 25, 1997 concerning Plant Explosions at Ethylene Oxide Sterilizers

Dear Ms. Diltz,

In response to your memorandum, the following is provided concerning the control technology in use at our sterilizer facility.

We have a Joslyn Sterilization System. The sterilization chamber, the chamber exhaust and Aeration Room were purchased in August 1991 and all control devices were installed on November 1, 1991.

The control unit consists of a 5 pallet stainless steel chamber, control consule/data acquisition, vacuum pumping module, heat exchanger system, circulation blower system, steam generator, sterilant transfer station, water chiller, water heater, recovery module, reprocessing module, scurbber module (acid-water scrubber), Gow gas sampling system. All areas are monitored by a HNU system which is an ETO monitoring system.

All equipment was purchased from Joslyn Sterilizer Corportation, 5815 Country Road 41, Farmington, NY. (Phone 1-716-398-2680).

We are titled under the Title V Air Quanlity General Permit. The facility had its last annual inspection on July 11, 1997 by Mr. Jeffery Winter from the Department of Regulatory and Environmental Services and Air Quality Division. The facility was found to be in compliance with DEP Rule 62-213.3000, Florida Administrative Code (F.A.C.).

Sincerely,

Jerry Bussell

Vice President Operations





Ms. Dotty Diltz Bureau of Air Monitoring & Mobile Sources Department of Environmental Protection Twin Towers Office Building 2600 Blair Stone Road Tallahassee, FL 323992-2400

3233376516

TITLE V AIR QUALITY GENERAL PERMIT INSPECTION SUMMARY REPORT

TYPE OF INSPECTION:	annual 🔀	COMPLAINT/I	DISCOVERY	RE-INSPECTION
TIME IN: 9.05	TIME OUT:	9.45	AIRS ID#:	0310379
TYPE OF FACILITY: Et	Lykne Oxide	2 Sterili	zer	
FACILITY NAME:	Comed Surg	ical Proc	Jucts	DATE: 7/11/97
FACILITY LOCATION:	6743 South	Point D	Dr. N.	. ,
Jac	cksouville, F	2 322	16	
RESPONSIBLE OFFICIAL:	Jerry Busse	11 , V. P.	PHONE NUMBER	(904)296-9600
	the compliance requiremen			acility is found to be in
Based on the results of discrepancies were note	the compliance requiremented:	ts evaluated during	this inspection, the f	ollowing compliance
COMPLIANCE REQ	UIREMENT/PROBL	EM FO	DLLOW-UP ACT	TON REQUIRED
•		٠.		
	_			
. ,				
				•
COMMENTS:				
•				•
	·			
The Annual Compliance Certific	action form has been proper	rly cortified and gul	hmittad to the inspect	or. YES NO
-	1	rly certified and sur	omitted to the inspect	or. resp NO
DATE OF NEXT INSPECTIO	IN: 34/	(Approximate) .	
INSPECTION CONDUCTED	BY: Jeff	Winter		
	111	(Please Print)		(a.) (a. allal
INSPECTOR'S SIGNATURE	- geffung.	Vinta.	_PHONE NUMBER	x: <u>(904)650-3484</u>
		ageof	·	Revised 10/96

AIRS ID#: 03/0379

THE REST. LIVE BEFT.

1D: 904 630 3638

Revised 10(10)

ETHYLENE OXIDE STERILIZERS
AIR QUALITY GENERAL PERMIT
ANNUAL COMPLIANCE CERTIFICATION FORM

AIR & WATER OUALITY DIVISION - CHY OF LACKSON VILLE

<u> </u>	W.Y. V.	
ODUCTS		M-7-16-91
T DRIVE N),	7.0
19 <u>96</u> то	July 11	<u>19</u> 97
criod covered by this	s statement. XYES	Пио
	to	
4.44		
ı continuous complia		period stated above:
	to	<u>^ ? ^ 1807 </u>
		0 L 0 1//
	Bureau & N	of Air Monitoring Mobile Sources
on and belief formed	l after reasonable inquir, Lean Bu	sell 7/16/97
	T DRIVE A 3221 1996 TO t, my facility has recorded covered by this continuous compliant continuous continuo	T DRIVE N. 32216 1996 TO TWY II t, my facility has remained in compliance with criod covered by this statement. YES continuous compliance during the reporting to to REC to Bureau 8 A and belief formed after reasonable inquiry

*This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.

Page of ____.

Revised 01/13/98

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ETHYLENE OXIDE STERILIZERS AIR QUALITY GENERAL PERMIT ANNUAL COMPLIANCE CERTIFICATION FORM

AIRS ID 0694823
INTERNATIONAL STERILIZATION
LABORATORY Y
MICHAEL MURPHY
217 SAMPEY ROAD
GROVELAND FL 34736

Bureau of Air Monitoring & Mobile Sources

ECET VEC

Do NOT Remove Label

Annual Reporting Period:	January 1	1997 то	December 31	1997
Based on each term or condition 62-213.300, Florida Administrat	_			DEP Rule
If NO, complete the following:				
#1. Term or condition of the gen	neral permit that has not b	een in continuous comp	oliance during the reporting po	eriod stated above:
Exact period of non-compliance	: from		to	
Action(s) taken to achieve comp	liance:			
Method used to demonstrate con	npliance:			
#2. Term or condition of the gen	neral permit that has not b	een in continuous comp	pliance during the reporting po	eriod stated above:
Exact period of non-compliance	: from		to	
Action(s) taken to achieve comp	liance:		_	
Method used to demonstrate con	npliance:			
As the responsible official, I here in this notification are true, accu		mation and belief forme	ed after reasonable inquiry, the	nat the statements made 02-/1-98 Date

^{*}This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.

Revised 01/13/98

ETHYLENE OXIDE STERILIZERS AIR QUALITY GENERAL PERMIT ANNUAL COMPLIANCE CERTIFICATION FORM

AIRS ID#0310379 XOMED SURGICAL PRODUCTS JERRY RUSSELL 6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216

_____/

	Do <u>NOT</u> Remo	ve Label			
Annual Reporting Period:	<u> </u>	19 ОТ ТО	ecember	31	_19 97
Based on each term or condition of the Title 62-213.300, Florida Administrative Code (F		•	<u></u> 4	ith DEP Rule	ı
If NO, complete the following:					
#1. Term or condition of the general permit	that has not been in cont	inuous compliance du	ring the reporting	g period stated	above:
Exact period of non-compliance: from		to			
Action(s) taken to achieve compliance:					
Method used to demonstrate compliance:		_			
#2. Term or condition of the general permit	that has not been in cont	inuous compliance du		•	
Exact period of non-compliance: from		to	N E C	CEIV	
Action(s) taken to achieve compliance:			F	EB 1 6 1998	}
Method used to demonstrate compliance:				of Air Monit Mobile Source	
As the responsible official, I hereby certify, made in this notification are true, accurate to RESPONSIBLE OFFICIAL: National Property Na	•	_ She	easonable inquiry MMU gnature	that the state	ments 198

^{*}This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.

PROFESER AIR QUALITY GENERAL PERMIT ANNUAL COMPLIANCE CERTIFICATION FORM



AIRS ID#0310379 XOMED SURGICAL PRODUCTS JERRY RUSSELL 6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216 Bureau of Air Monitoring & Mobile Sources

Do NOT Remove Label

Annual Reporting Period: TANU	424 1	19 97 то	Pecember	31	_19 97
Based on each term or condition of the Tit	-				
If NO, complete the following: #1. Term or condition of the general pern	nit that has not been	in continuous complia	ance during the reporting	ng period stated	above:
Exact period of non-compliance: from		_	_ to		
Action(s) taken to achieve compliance:					
Method used to demonstrate compliance:					
#2. Term or condition of the general perm	uit that has not been i	in continuous complia	ance during the reporting	ng period stated	above:
Exact period of non-compliance: from			to_		
Action(s) taken to achieve compliance:		•			
Method used to demonstrate compliance:					
As the responsible official, I hereby certify, be notification are true, accurate and complete. does not exceed 2,100 gallons per year for dry	Further, my annual c	onsumption of perchlo	roethylene solvent, based	l upon purchase i	
RESPONSIBLE OFFICIAL: Tem	Busseur ame (Please Print)		Signature	2/12/ Dat	98 e

^{*}This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.

ETHYLENE OXIDE STERILIZERS

TITLE V GENERAL PERMIT COMPLIANCE INSPECTION CHECKLIST

TYPE OF INSPECT	rion: Annual re-inspec	TION	× -	COMPLAINT/DISCOVERY	
AIRS ID#:	Xomed	I Su	rgical	TIME OUT: 9:49 Products Point Dr. N. FL 32216	
PART I: NOTIFIC	ATION				
_	ARM by 9/1/96 ARM 30 days prior to setup tify DARM to use a genera				×
PART II: CONTRO	OL TECHNOLOGY				
Vent type(s) at the f	Steriliza Chambo				
Has one of the follow		ces been	installed? I	If yes, indicate type below.	ומ□
	Acid-Water Scrubber			Oxidation Unit	
	Catalytic Oxidation Unit	Ø		ECOVERY SYSTEM	
	,		(Must submit	information to DEP for approval)	
Chamber Exhaust			(Must submit	information to DEP for approval)	
		easuremen:		information to DEP for approval) .	
☐ No emission con	<u>Vent</u>		t in Part III)		
□ No emission con □ Emissions mani	Vent trol device. (must use direct m	iber vent	t in Part III) control dev		
□ No emission con □ Emissions mani	Vent trol device. (must use direct m folded to sterilization chan	iber vent	i in Pari III) control dev low).		

PART III: MONITORING REQUIREMENTS			-
Has the facility conducted an initial performance test? (Existing facilities by 6/8/98, new sources within 180 days after startup)	×	¥	□N
Acid-Water Scrubbers			
What process parameter is the facility monitoring to determine compliance?			
Lethylene glycol concentration scrubber liquor tank level			
If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?	4	a	MN
Catalytic/Thermal Oxidation Units			
Has the facility installed a temperature sensor that is accurate to within \pm 10° F?		ÌΥ	□N
Has the facility verified the accuracy of the temperature sensor? (must be performed semiannual)	y) 🗆	ÌΥ	□N
Direct Measurement			
Has the facility installed a gas chromatograph?	×	(Y	□N
PART IV: RECORDKEEPING REQUIREMENTS			
Has the facility maintained the following records?			
Owner's manuals, designs specifications, and other instructional materials for the sterilization unit and control equipments.	XY	□N	
Records of ethylene oxide usage on a 12-month rolling average.	X Y	ΠN	
Records of all initial performance tests, including control efficiency determinations.	X	ΠN	
Records of all temperature monitoring. (oxidation units only)	$\Box Y$	ΠN	XXN/A
Records of all ethylene oxide concentration monitoring. (direct measurement only)	ПY	ΠN	MN/A
Records of gas chromatograph calibration (direct measurement only)	X Y	ΠN	□N/A
Records of scrubber liquor level. (acid-water scrubbers only)	May !	AN.	□N/A
Records of ethylene glycol concentration. (acid-water scrubbers only)	ωY .		MN/A
PART V: ADDITIONAL SITE INFORMATION			
·			
			'
·			

Additional Site Information, cont.	
	<u> </u>
J 2 1	
Jerry Bussell	
Name of Responsible Official	-1.1/2-
Jeff Winter	
Inspector's Name	Date of Inspection
Jeffry lind	<u> </u>
Aspector's Signature	Approximate Date of Next Inspection

3 of 3

ETHYLENE OXIDE STERILIZERS

TITLE V GENERAL PERMIT **COMPLIANCE INSPECTION CHECKLIST**

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						PET.	
	ETHYLE	NE OXII	DE STI	ERILIZERS	S	CA	11
		TLE V GENI NCE INSPI		RMIT CHECKLIST	Bure B.	SEP 5 5 10	P.A.
TYPE OF DISPECT			√			Max Av 9 19	
TYPE OF INSPECT		ECTION	<i>)</i> ≃. □	COMPLAIN	T/DISCOVERY/	Poblic Shorts	σ
	KL-INSI	LCTION				Solregor	ne Ne
AIRS ID#: <u>03/</u>					_ TIME OUT:	1045	ľ
FACILITY NAME:	Xome	d Surg	ical	Product	3		
FACILITY LOCAT	TION: 6743	3 Sout	4 Poin	+ Dr. 1	<i>!</i> .		
	Jac	KSON VI	ille, i	FL 32	216		
RESPONSIBLE OF	_				704) 296-9	7600	
	Pollin	P.Can	1:44		XT. 2099		·
CONTACT NAME:	year.	<u> D</u> an	(/ / (PHONE: <u>-~</u>	r. 2011		
	† <u></u>						•
PART I: NOTIFIC	ATION						<i>.</i> I
Facility notified DA	ARM 30 days prior to se	etup				×	
·	ARM 30 days prior to sentify DARM to use a gen	-				×	
·		-				-	
Facility failed to no		-				-	
Facility failed to no	DL TECHNOLOGY acility: Aera	neral permit				-	
Facility failed to no	DL TECHNOLOGY Cacility: A Aera	neral permit tion Room				-	
Facility failed to no	DL TECHNOLOGY Cacility: A Aera	neral permit				-	
PART II: CONTRO Vent type(s) at the f	DL TECHNOLOGY Cacility: Aera Steri Char Char	neral permit tion Room lization Char mber Exhaust	i				
PART II: CONTRO Vent type(s) at the f	DL TECHNOLOGY Facility: A Aera Steri	neral permit tion Room lization Char mber Exhaust	nstalled?		/pe below. ≱		
PART II: CONTRO Vent type(s) at the f	DL TECHNOLOGY Cacility: Aera Steri Char Char	neral permit tion Room lization Char mber Exhaust	nstalled?	Oxidation Unit			
PART II: CONTRO Vent type(s) at the f Sterilization Cham Has one of the follo	DL TECHNOLOGY Tacility: Aera Steri Char There Vent Wing emission control desired.	tion Room lization Char mber Exhaust levices been in	nstalled? Thermal (YSTEM		
Facility failed to not part II: CONTRO Vent type(s) at the facility of the following serious control of the following serious contr	DL TECHNOLOGY Cacility: Aera Steri Char wing emission control de Acid-Water Scrubber Catalytic Oxidation United	tion Room lization Char mber Exhaust levices been in	nstalled? Thermal (Oxidation Unit ECOVERY S	YSTEM		
PART II: CONTRO Vent type(s) at the f Sterilization Cham Has one of the follo Chamber Exhaust	DL TECHNOLOGY Cacility: Aera Steri Char wing emission control de Acid-Water Scrubber Catalytic Oxidation United	tion Room lization Char mber Exhaust levices been in	nstalled? Thermal (Other <u>R</u> (Must submit	Oxidation Unit ECOVERY S	YSTEM		
Facility failed to not part II: CONTRO Vent type(s) at the face of the following part o	DL TECHNOLOGY Cacility: Aera Char	tion Room lization Char mber Exhaust levices been in	nstalled? Thermal (Other K (Must submit	Dxidation Unit	YSTEM		
Facility failed to not provide the failed the fai	DL TECHNOLOGY Facility: A Aera Steri Char wing emission control de Acid-Water Scrubber Catalytic Oxidation University Vent atrol device. (must use direction)	neral permit Ition Room Iization Char Iization Exhaust Ievices been in Init Init Init	nstalled? Thermal (Other (Must submit in Part III)	Dxidation Unit	YSTEM		
Facility failed to not provide the facility failed to not provide the facility of the facility	DL TECHNOLOGY Facility: Aera Steri Char Sher Vent wing emission control of Acid-Water Scrubber Catalytic Oxidation Univent atrol device. (must use directed) folded to sterilization characteristics.	tion Room lization Char mber Exhaust levices been in it ct measurement in namber vent coate type belo	nstalled? Thermal (Other (Must submit in Part III) control dev	Dxidation Unit	YSTEM		
Facility failed to not provide the facility failed to not provide the facility of the facility	DL TECHNOLOGY Cacility: Aera Steri Chan wing emission control de Acid-Water Scrubber Catalytic Oxidation United Actor device. (must use direct folded to sterilization chion control device (indicator)	tion Room lization Char mber Exhaust levices been in ct measurement in namber vent co cate type belo	nstalled? Thermal (Other K (Must submit in Part III) control dev ow). Thermal (Other	Oxidation Unit	for approval)		

PART III: MONITORING REQUIREMENTS			
Has the facility conducted an initial performance test? (Existing facilities by 6/8/98, new sources within 180 days after startup)		Z Y	□N
Acid-Water Scrubbers			
What process parameter is the facility monitoring to determine compliance?			
ethylene glycol concentration scrubber liquor tank level			
If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?	(□Y	□N
Catalytic/Thermal Oxidation Units			
Has the facility installed a temperature sensor that is accurate to within \pm 10° F?	ſ	ΠY	□N
Has the facility verified the accuracy of the temperature sensor? (must be performed semiannual)	<i>y)</i> [⊐Y	□N
<u>Direct Measurement</u>			
Has the facility installed a gas chromatograph?	(⊐Y	□N
PART IV: RECORDKEEPING REQUIREMENTS			
Has the facility maintained the following records?			
Owner's manuals, designs specifications, and other instructional materials for the sterilization unit and control equipments.	XY	□N	
Records of ethylene oxide usage on a 12-month rolling average.	X Y	□N	
Records of all initial performance tests, including control efficiency determinations.	X Y	□N	
Records of all temperature monitoring. (oxidation units only)	XY	□N	□N/A
Records of all ethylene oxide concentration monitoring. (direct measurement only)	XΥ	□N	□N/A
Records of gas chromatograph calibration (direct measurement only)	ПY	□N	M/A
Records of scrubber liquor level. (acid-water scrubbers only)	X Y	□N	□N/A
Records of ethylene glycol concentration. (acid-water scrubbers only)	X Y	□N	□N/A
	•		
Tomaliano			
Inspector's Name Date of Inspec			
		20	
Inspector's Signature Approximate Date of Ne		7 ection	
Instructor's Signature Approximate Date of Ne	at msp	SCHOIL	

PART V: ADDITIONAL SITE INFORMATION				
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		·		

TITLE V AIR QUALITY GENERAL PERMIT INSPECTION SUMMARY REPORT

TYPE OF INSPECTION: ANNUAL X	COMPLAINT/DISCOVERY RE-INSPECTION
TIME IN: 9'50 TIME OUT:	10:45 AIRS ID#: 03/0379
TYPE OF FACILITY: Ethylene Oxide	Sterilization Facility,
FACILITY NAME: Xomed Surgica	Products DATE: 9/4/98
FACILITY LOCATION: 6743 SOUTH	Point Dr. N.
Jacksonville	, FL 32216
RESPONSIBLE OFFICIAL: Jerry Busse 1	PHONE NUMBER: 904-296-9600
Based on the results of the compliance requirements et compliance with DEP Rule 62-213.300, Florida Admi	valuated during this inspection, the facility is found to be in nistrative Code (F.A.C.).
Based on the results of the compliance requirements endiscrepancies were noted:	valuated during this inspection, the following compliance
COMPLIANCE REQUIREMENT/PROBLEM	FOLLOW-UP ACTION REQUIRED
	J
	Prcx
	Bureau SEP 2 L FO
	Solitos Monitorine
COMMENTS:	
·	
The Annual Compliance Certification form has been properly of	certified and submitted to the inspector. YES NO
DATE OF NEXT INSPECTION:	19UST, 1999
INSPECTION CONDUCTED BY:	(Approximate) (Please Print)
INSPECTOR'S SIGNATURE:	PHONE NUMBER: 904-630-2800
/ U/ Page	of / Revised 10/96

ETHYLENE OXIDE STERILIZERS

TITLE V GENERAL PERMIT COMPLIANCE INSPECTION CHECKLIST

RECEIVED

	ANNUAL	PL .	COMPLAINT/DISC	^{2R2} 2 199 9
· ·	RE-INSPECTION		Bureau o & Mo	of Air Monitoring
AIRS ID#: 03/0379	DATE: 7/30	99 TIME		UT: <u>/030</u>
FACILITY NAME:	Xomec	1 Surg	rical Produ	icts .
FACILITY LOCATION: _	6743	Sout	h foint Dr.	<i>N</i>
	Jacks	on ville	, FL. 3221	<i>'</i> 6
RESPONSIBLE OFFICIAL : _	Jerry 1	Bussell	PHONE: 904/2	96-960
CONTACT NAME:	ebbie Bra	mlitt	PHONE: 904/296	-9600
PART I: NOTIFICATION				
Facility notified DARM 30 days	•	•.		784
Facility failed to notify DARM	to use a general permi	it 		
PART II: CONTROL TECHNO	OLOGY			
Vent type(s) at the facility:	☐ Aeration Room			
	☐ Sterilization Ch			·
·	S Charles Falls			
II .	Chamber Exna	ust		
Sterilization Chamber Vent	Chamber Exha	ust		
Sterilization Chamber Vent Has one of the following emission	•		yes, indicate type below.	My □N
•	on control devices bee		-	yky □n
Has one of the following emission	on control devices bee	n installed? If Thermal Ox Other	kidation Unit	
Has one of the following emission	on control devices bee	n installed? If Thermal Ox Other	-	
Has one of the following emissic Acid-Water Catalytic O	on control devices bee Scrubber xidation Unit	n installed? If Thermal Ox Other (Must submit to	kidation Unit	
Has one of the following emissic Acid-Water Catalytic O Chamber Exhaust Vent	on control devices bee - Scrubber xidation Unit must use direct measurement	n installed? If Thermal Ox Other (Must submit is	kidation Unit	
Has one of the following emission Acid-Water Catalytic O Chamber Exhaust Vent No emission control device.	on control devices bee - Scrubber xidation Unit must use direct measureme	n installed? If Thermal Ox Other (Must submit in ent in Part III) t control device	kidation Unit	
Has one of the following emission Acid-Water Catalytic O Chamber Exhaust Vent No emission control device. (Emissions manifolded to ster	on control devices bee Scrubber xidation Unit Smust use direct measurement ilization chamber venice (indicate type be	n installed? If Thermal Ox Other (Must submit in ent in Part III) t control device elow).	kidation Unit	

PART III: MONITORING REQUIREMENTS	-	
Has the facility conducted an initial performance test? (Existing facilities by 6/8/98, new sources within 180 days after startup)	A	Z
Acid-Water Scrubbers		
What process parameter is the facility monitoring to determine compliance?		
ethylene glycol concentration scrubber liquor tank level		
If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?	□Y	¥N
Catalytic/Thermal Oxidation Units		
Has the facility installed a temperature sensor that is accurate to within ± 10° F?	YY	ПN
Has the facility verified the accuracy of the temperature sensor? (must be performed semiannually) Direct Measurement	Y	OΝ
Has the facility installed a gas chromatograph?	XY	חם

PART IV: RECORDKEEPING REQUIREMENTS Has the facility maintained the following records? Owner's manuals, designs specifications, and other instructional materials for the sterilization unit and control equipments. ПN Records of ethylene oxide usage on a 12-month rolling average. Records of all initial performance tests, including control efficiency determinations. $\square N$ ПИ □N/A Records of all temperature monitoring. (oxidation units only) □N/A Records of all ethylene oxide concentration monitoring. (direct measurement only) Records of gas chromatograph calibration (direct measurement only) □N/A Records of scrubber liquor level. (acid-water scrubbers only) □N/A Records of ethylene glycol concentration. (acid-water scrubbers only) □N/A

Inspector's Name

Date of Inspection

July 2000

Approximate Date of Next Inspection

PART V: ADDITIONAL SITE INFORMATION				
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TITLE V AIR QUALITY GENERAL PERMIT INSPECTION SUMMARY REPORT

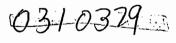
TYPE OF INSPECTION:	ANNUAL 💢	COMPLAIN	T/DISCOVERY	RE-INSPECTION D
TIME IN: 945	TIME OUT:	103	O AIRS ID#:	0340379
TYPE OF FACILITY:	thylene Oxi	de Ste	erilizer	Mobile Air Man
FACILITY NAME: X	orned Surgic	al Pro	ducts	DATE: 7/30/199
FACILITY LOCATION:	6743 SOU-	th Point	+ Dr. N.	, Fes me
	Jack Son VI	Ile, FC	- 32216	
RESPONSIBLE OFFICIAL:	Derry B	ussell	PHONE NUMBE	R: 904/296-9600
	the compliance requirement Rule 62-213.300, Florida Ac			facility is found to be in
Based on the results of discrepancies were note	the compliance requiremented:	s evaluated dur	ing this inspection, the	following compliance
COMPLIANCE REQU	JIREMENT/PROBLE	EM	FOLLOW-UP AC	TION REQUIRED
		ii		
	•			·
COMMENTS:				
				<u> </u>
The Annual Compliance Certific	cation form has been proper	ly certified and	submitted to the inspect	tor. YES NO
DATE OF NEXT INSPECTIO)N:	JUM	,2000	
·		(Approxim	,	
INSPECTION CONDUCTED	BY: 26	11 000	nter	
77077 CTC 712 CTC 712	Culling 1	(Please Pri	•	9n4/12n-2UR4
INSPECTOR'S SIGNATURE	:	mio	PHONE NUMBE	K: /V// W/V- 270/
	Pa	geof		Revised 10/96



ETHYLENE OXIDE STERILIZERS AIR QUALITY GENERAL PERMIT

AIRS ID#: 03/0379	R. C.	Revised 10/10/96
AIR QUALITY	XIDE STERILIZERS GENERAL PERMI ICE CERTIFICATION F	T Sures PA 2 FA
	thfoint Dr. A	DATE: 4739/99
	e, FL 3221	
Annual Reporting Period:	19 <i>_98 t</i> o	JUly 50, 19 77
Based on each term or condition of the Title V general air per 62-213.300, Florida Administrative Code (F.A.C.), during the		\ - /
If NO, complete the following:		
#1. Term or condition of the general permit that has not been	in continuous compliance duri	ng the reporting period stated above:
Exact period of non-compliance: from	to	
Action(s) taken to achieve compliance:	_	
Method used to demonstrate compliance:		
#2. Term or condition of the general permit that has not been	i in continuous compliance duri	ng the reporting period stated above:
Exact period of non-compliance: from	to	
Action(s) taken to achieve compliance:		
Method used to demonstrate compliance:		
As the responsible official, I hereby certify, based on informa made in this notification are true, accurate and complete.	LL 4	sonable inquiry, that the statements
RESPONSIBLE OFFICIAL: Name (Please Print)	Sign	ature P-8-29 Date

^{*}This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.





Date: MY 17.19

Month/day/yr

Initial Notification Report

Subpart O--National Emission Standards for EO Commercial Sterilization and Fumigation Operations

Effective date:

December 8, 1994

All facilities using 1 ton or more of ethylene oxide (EO) per year are required to submit this notification. See section 63.366 of subpart O and section 63.9 of subpart A.

The initial notification should be submitted to the appropriate authority within 120 days after the effective date (120 days after the effective date is April 8, 1995) or within 120 days after initial startup, whichever is later.

taki ik tirittara kenara yan bilan bilan dalam Print or type the following for each plant in which EO commercial sterilization and fumigation operations are performed:

Name	of Owner/O	perator ;					
Maili	ing Address	674	350	THEOIL	ST DR	WE WORT	H
City.	-JACKSON	WILE	State	FLORIT	A	Zip Code 322	1
Plant	Name 🔀	DMED			·		
Plant	Address (if differ	ent thar	owner/ope	erator's)	
Stree	et Address	*					
City	-		State			Zip Code	
	Number _						
Plant	Contact/T	itle	_				
		that are nd labora	exempt	from subpa	art O are	igation e those used f n 112(c)(7) of	
2.	Note the i	nitial st	artup da	ite for the	source	11-92	

The date of promulgation in the Federal Register.

Plant Name: XOMED

3. Check the boxes that apply; note the compliance date.2

Compliance Date

Initial startup occurred on or before December 8, 1997.

Same and the same of the same

December 8, 1997

Initial startup occurred after December 8, 1997.

(compliance date =
initial startup date)

The facility uses 10 tons of EO or more per year.

The facility uses 1 to 10 tons of EO per year

4. Complete the following table for each vent type (i.e., sterilization chamber or aeration room). If additional space is needed, make copies of this page. The first row of each section gives examples of appropriate entries.

Vent type	Sterilization chamber size (m³)	No. of chambers of this size
Sterilization chambers	Example - 30 m ³	2
CUMULATIVE STER	ILIZATION CHAMBER SIZE (m ³): ^a
Vent type	Aeration room or aeration chamber size	No. of rooms or chambers of this size
Aeration rooms or aeration chambers	Example - 280 m ³	

Summation of the volume of all sterilization chambers at the facility.

680. H.3

²The date a source is required to be in compliance with the Ethylene Oxide Commercial Sterilization and Fumigation NESHAP.

Plant Name: XOMED

5. Complete the following table. If additional space is needed, make copies of this page. The first three rows give examples of appropriate entries.

Vent type: (e.g., SCV, ARV, CEV)	. Applicable emission limitation
Example - two SCV (30 m ³)	99% emission reduction
Example - one ARV (280 m ³)	99% emission reduction
Example - two CEV (30 m ³)	5,300 ppmv
J 56V	
1-CEV	
1- ARV	

SCV = sterilization chamber vent (includes sterilization chamber vacuum pump); ARV = aeration room vent; CEV = chamber exhaust vent (also referred to as back draft or door hood vent).

Emission limitations could be: 99% emission reduction; 1 ppmv concentration limit or 99% emissions reduction; or 5,300 ppmv concentration limit.

- 6. Emissions from the sterilization chamber vacuum pump will be controlled as follows (check one):
 - Emissions will be vented to a control device (i.e., control device for the sterilization chamber vent) and will be reduced by 99 percent.
- A recirculating-fluid vacuum pump will be used.
- 7. Attach additional pages including any other information required by the State or local agency.

Plant Name: XOMED

8. Print or type the name and title of the Responsible Official for the plant:

BERT KEENE FACILITY MANAGER

Name

i.

Title

A Responsible Official can be:

- The president, vice-president, secretary, or treasurer of the company that owns the plant;
- The owner of the plant;
- The plant engineer or supervisor; or
- A government official if the plant is owned by the Federal, State, City, or County government.

The Responsible Official <u>must</u> certify below that all of the information presented in this initial report is accurate and true.

I certify the information contained in this report to be accurate and true to the best of my knowledge.

Bouttoone

6-13-95

Signature of Responsible Official

Date

BEST AVAILABLE COPY

ETHYLENE OXIDE STERILIZERS TITLE V GENERAL PERMIT

	COMPLIANCE	EINSPEC	CTION C	HECKLIST *	C	107 144	
TYPE OF INSPECTION:	ANNUAL		A	COMPLATA)	r/discov e j	3Y \	
	RE-INSPECTI	ON	–	& Mora	2 > 2000	RO VI	
AIRS ID#: <u>03/03</u> 7	9 DATE: 6/2	26/200	<u> </u>	IN: 1030%	TIME OU	T: <u>//00</u>	
FACILITY NAME: X O'MED SUYgical Products							
FACILITY LOCATION: 6743 South Point Drive N.							
	Jackse	nville	'e, F	- 322	16		
RESPONSIBLE OFFICIAI	: Jerry	BUSS	ell	_ PHONE:	04-296	-9600	
Tack Son ville, FL 32216 RESPONSIBLE OFFICIAL: <u>Jelly Bussell</u> PHONE: 904-296-9600 CONTACT NAME: <u>Dellive Branlitt</u> PHONE: 904-296-9600							
PART I: NOTIFICATION							
Facility notified DARM 30 days prior to setup					×		
Facility failed to notify DARM to use a general permit							
PART II: CONTROL TEC	HNOLOGY	,					
Vent type(s) at the facility:	Aeration R	.oom					
	Sterilizatio	n Chambe	er				
	Chamber E	Exhaust				!	
Sterilization Chamber Ven	<u>t</u>						
Has one of the following em	ission control devices	been inst	alled? If	yes, indicate typ	e below.	Y DN	
Acid-W	Vater Scrubber	☐ Th	ermal Ox	idation Unit		•	
☐ Catalyt	ic Oxidation Unit		her	nformation to DEP	for approval)		
Chamber Exhaust Vent		(1411	431 3HOMII I	njormation to DET j	or upprovaty		
No emission control devi	Ce. (must use direct measi	urement in F	art III)				
Emissions manifolded to	Emissions manifolded to sterilization chamber vent control device.						
Dedicated emission contr	1.1. 2. 2. 154-4					l l	
	oi device (indicate tyl	pe below)					
Acid-W	of device (indicate typ /ater Scrubber			idation Unit			

PART III: MONITORING REQUIREMENTS		
Has the facility conducted an initial performance test? (Existing facilities by 6/8/98, new sources within 180 days after startup)		□N
Acid-Water Scrubbers		
What process parameter is the facility monitoring to determine compliance?		
ethylene glycol concentration scrubber liquor tank level		
If the facility is monitoring the scrubber liquor tank level, has a liquid level indicator been installed?	¥¥v	□N
Catalytic/Thermal Oxidation Units		
Has the facility installed a temperature sensor that is accurate to within ± 10° F?		□N
Has the facility verified the accuracy of the temperature sensor? (must be performed semiannually)		□N
Direct Measurement		
Has the facility installed a gas chromatograph?	Agr	□N

PART IV: RECORDKEEPING REQUIREMENTS Has the facility maintained the following records? Owner's manuals, designs specifications, and other instructional materials for $\square N$ the sterilization unit and control equipment. $\square N$ Records of ethylene oxide usage on a 12-month rolling average. $\square N$ Records of all initial performance tests, including control efficiency determinations. \square N □N/A Records of all temperature monitoring. (oxidation units only) ΠN Records of all ethylene oxide concentration monitoring. (direct measurement only) □N/A Records of gas chromatograph calibration (direct measurement only) □N □N/A MN/A Records of scrubber liquor level. (acid-water scrubbers only) \square N □N/A Records of ethylene glycol concentration. (acid-water scrubbers only)

Inspector's Name

Date of Inspection

July Luter

Dispector's Signature

Approximate Date of Next Inspection

PART V: ADDITIONAL SITE INFORMATION		

TITLE V AIR QUALITY GENERAL PERMIT INSPECTION SUMMARY REPORT

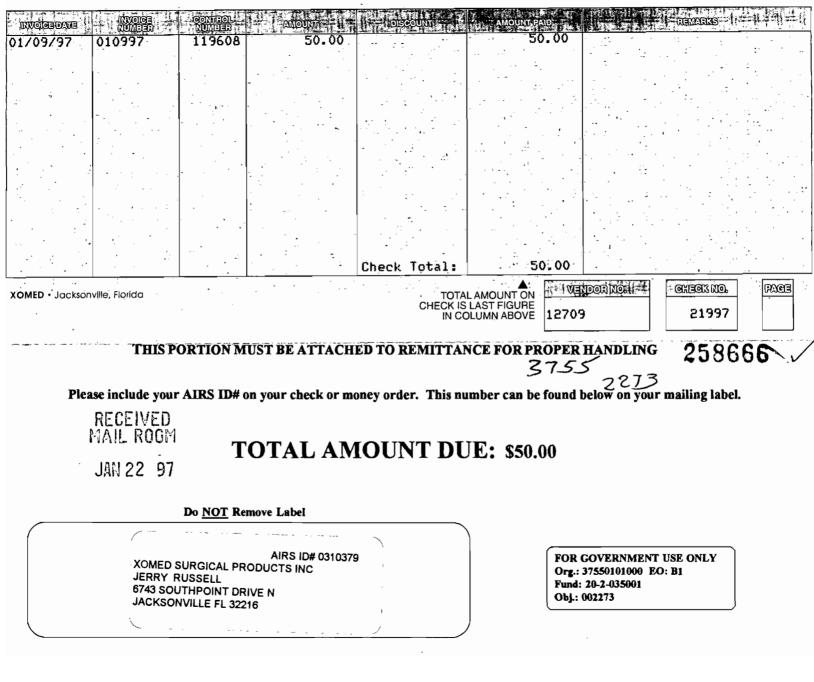
TYPE OF INSPECTION: ANNUAL X COM	PLAINT/DISCOVERY RE-INSPECTION				
TIME IN: 1030 TIME OUT: //	00AIRS ID#: 03/0379				
TYPE OF FACILITY: Ethylene Oxide S	tecilizer				
FACILITY NAME: Xorned Surgical	froducts DATE: 6/26/2000				
FACILITY LOCATION: 6743 SOUTL POIN	nt Dr. N.				
Jack Sonville, Fo	322/6				
RESPONSIBLE OFFICIAL: SUITE BUSSELL	PHONE NUMBER: 904-279-7587				
Based on the results of the compliance requirements evalua compliance with DEP Rule 62-213.300, Florida Administra					
Based on the results of the compliance requirements evalua discrepancies were noted:	ted during this inspection, the following compliance				
COMPLIANCE REQUIREMENT/PROBLEM	FOLLOW-UP ACTION REQUIRED				
·					
-					
COMMENTS:					
	——————————————————————————————————————				
The Annual Compliance Certification form has been properly certified and submitted to the inspector. YES NO					
DATE OF NEXT INSPECTION: JUNE	oroximate)				
INSPECTION CONDUCTED BY: Jeff	Vinter				
	ase Print)				
INSPECTOR'S SIGNATURE: My Inte	PHONE NUMBER: 904-630-1212				
Page lo	f Revised 10/96				

AIRS ID#: 03/0379

ETHYLENE OXIDE STERILIZERS AIR QUALITY GENERAL PERMIT

ANNUAL COMPLIANCE CERTIF	FICATION FORM
FACILITY NAME: Xomed Surgical Product	DATE: 120/2000
FACILITY LOCATION: 6743 South Birt Dr	ive N.
Jacksonville, FL 3	32216
Annual Reporting Period: July 30 1999	то <u>June 26, 2000</u>
Based on each term or condition of the Title V general air permit, my facility 62-213.300, Florida Administrative Code (F.A.C.), during the period covered	
If NO, complete the following:	•
#1. Term or condition of the general permit that has not been in continuous of	compliance during the reporting period stated above:
Exact period of non-compliance: from	to
Action(s) taken to achieve compliance:	
Method used to demonstrate compliance:	
#2. Term or condition of the general permit that has not been in continuous of	compliance during the reporting period stated above:
Exact period of non-compliance: from	to
Action(s) taken to achieve compliance:	
Method used to demonstrate compliance:	
As the responsible official, I hereby certify, based on information and belief is made in this notification are true, accurate and complete. RESPONSIBLE OFFICIAL: Name (Please Print)	Signature Date

^{*}This form is made available to you as an aid in order to meet your annual compliance certification requirements. It is at the discretion of the responsible official to use this form.



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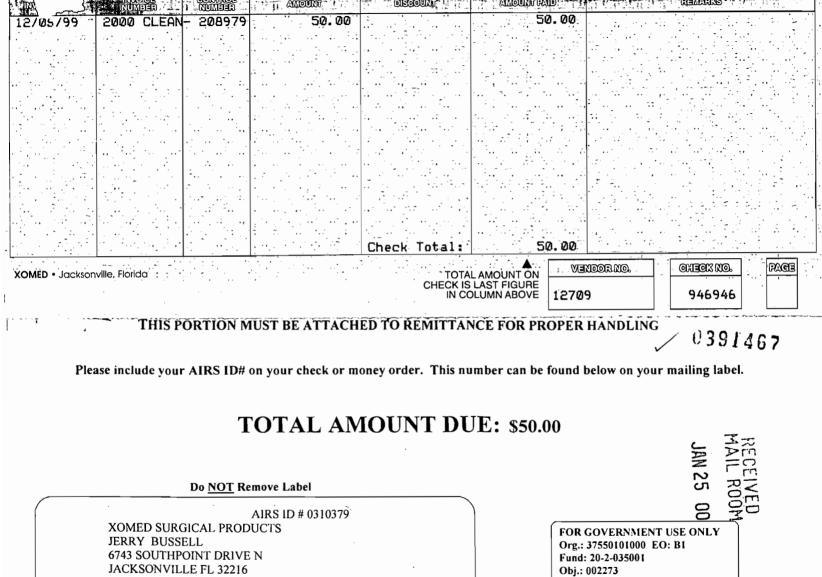
US Postal Service
Receipt for Certified Mail

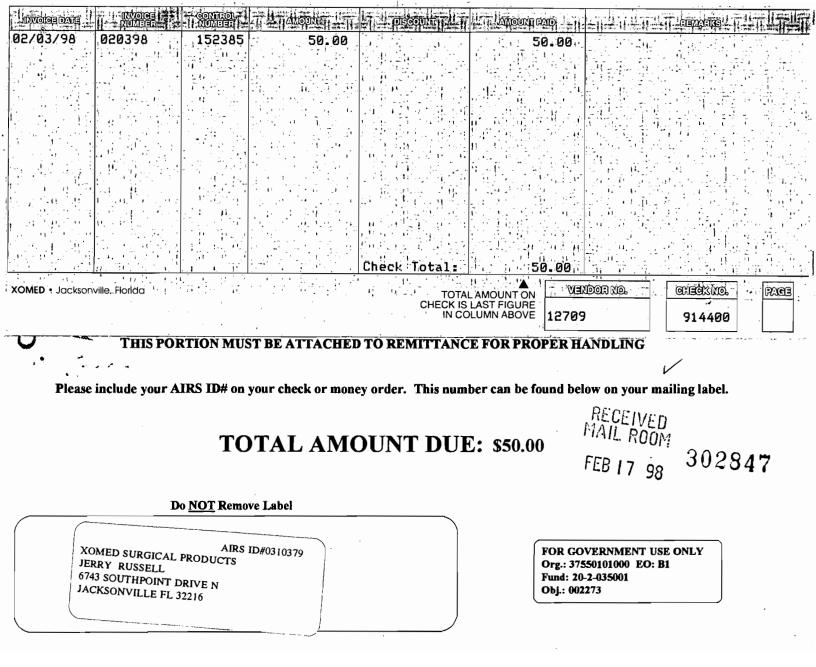
AIRS ID 0310379

XOMED SURGICAL PRODUCTS
JERRY RUSSELL
6743 SOUTHPOINT DRIVE N
JACKSONVILLE FL 32216

	Postage	\$	
	Certified Fee	-	
	Special Delivery Fee		
	Restricted Delivery Fee		
April 1995	Return Receipt Showing to Whom & Date Delivered		
	Return Receipt Showing to Whom, Date, & Addressee's Address		
800	TOTAL Postage & Fees	\$	
PS Form 3800, April 1995	Postmark or Date		

on the reverse side?	SENDER: Complete items 1 and/or 2 for additional services. Complete items 3, 4a, and 4b. Print your name and address on the reverse of this form so that we card to you Attach this form to the front of the mailpiece, or on the back if spacemit. Write "Return Receipt Requested" on the mailpiece below the article The Return Receipt will show to whom the article was delivered and delivered.	I also wish to receive following services (extra fee): 1. Addressee 2. Restricted Consult postmaster	for an 's Address	
N ADDRESS completed of	3. Article Addressed to: AIRS ID 0310379 XOMED SURGICAL PRODUCTS JERRY RUSSELL 6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216	4b. Service 1 Registere Express N Return Rec	Type Ind Mail Sepipt for Merchandise	Cop Cop
RETUR	5. Received By: (Print Name)		s's Address (Only if r	ednested by
ls your	6. Signature: (Addressee or Agent) - X U-Russee or Agent) PS Form 3811, December 1994	2595-97-B-0179	Domestic Return	n Receipt





	U.S. Postal Service CERTIFIED MAIL RECEIPT (Domestic Mail Only; No Insurance Coverage Provided)			
267				
12	- OPELO:AL, D多園 - I			
75	Postage \$			
79.	Certified Fee			
[]	Return Receipt Fee (Endorsement Required)			
000	Restricted Delivery Fee (Endorsement Required)			
50	Total Postage & Fees \$			
03	Sent To AIRS ID#0310379			
]	METRONIC XOMED			
	Street, Apt. No.; JERRY BUSSELL or PO Box No. 6743 SOUTHPOINT DRIVE N			
7007	City, State, ZIP+4 JACKSONVILLE FL			
<u>L</u>	932216 PS Form 3800, J			

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY
 Complete items 1, 2, and 3. Also complete item 4 if Restricted Deliyery is desired. Print your name and address on the reverse so that we can return the card to you. Attach this card to the back of the mailpiece, or on the front if space permits. 	A. Received by (Please Print Cleady) B. Date of Delivery O. Signature X
Article Addressed to: AIRS ID#0310379 METRONIC XOMED JERRY BUSSELL	If YES, enter delivery address below:
6743 SOUTHPOINT DRIVE N JACKSONVILLE FL	3. Service Type
32216	☐ Certified Mail ☐ Express Mail ☐ Registered ☐ Return Receipt for Merchandise ☐ Insured Mail ☐ C.O.D.
	4. Restricted Delivery? (Extra Fee)
Article Number (Copy from service label)	7001 0320 0001 7975 5267
Form 3811, July 1999 Domestic	Return Receipt 102595-00-M-0952

UNITED STATES POSTAL SERVICE: NILL First-Class-Mail Postage & Fees Paid USPS Permit No. G-10

• Sender: Please print vour name, address, and ZIP+4 in this box 20

DARM/MOBILE SOURCE CONTROL PROGRAMMIE SOURCE CONTROL PROGRAMMIE



THIS PORTION MUST BE ATTACHED TO REMITTANCE FOR PROPER HANDLING

Please include your AIRS ID# on your check or money order. This number can be found below on your mailing label.

TOTAL AMOUNT DUE: \$50.00

Do NOT Remove Label

AIRS ID#0310379

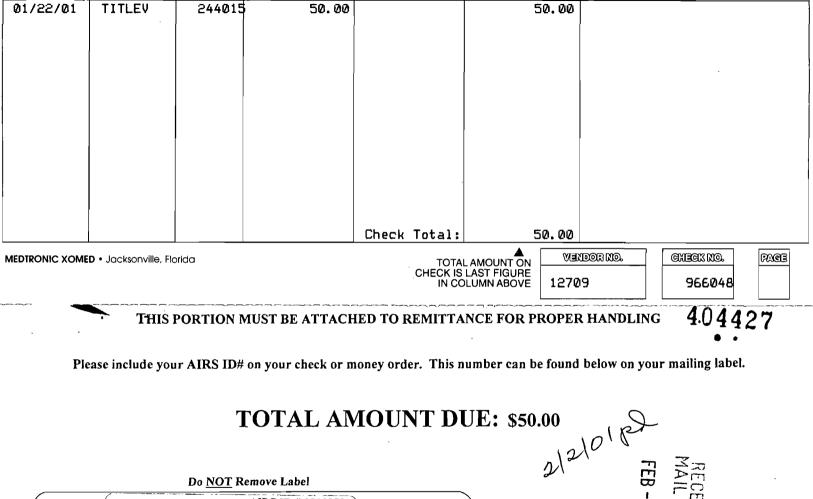
METRONIC XOMED JERRY BUSSELL 6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216

A Pre	edtronic	1177		PT OF ENVIRONM	ENTAL		_1032394	6
VOUCHER NUMBER	INVOICE NUMBER	PURCHASE ORDER	INVOICE DATE	AMOUNT	DISCOUNT	NET AMOUNT	DESCRIPTION	1
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		When Li	ê Depem	ts on Mes.	ical Techn	rology		
TOTALS			7	50.00	0.00	50.00		

Medtronic

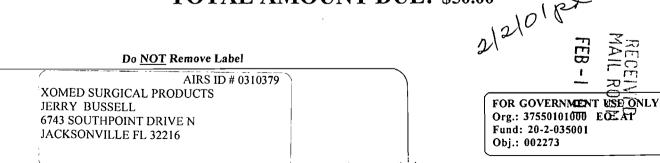
Medtronic, Inc. Shared Service Center Attn: Accounts Payable 3850 Victoria Street North Shoreview, MN 55126-2978

DEPT OF ENVIRONMENTAL PROTECTION PO BOX 3070 TALLAHASSEE FL 32315



AMOUNT PAID

REMARKS



CONTROL NUMBER

AMOUNT

Z 210 663 195

US Postal Service

Receipt for Certified Mail

No Insurance Coverage Provided.

Do not use for International Mail (See reverse)

AIRS ID # 0310379001AG JERRY BUSSELL XOMED SURGICAL PRODUCTS 6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216

	Certified Fee	
	Special Delivery Fee	
	Restricted Delivery Fee	
1995	Return Receipt Showing to Whom & Date Delivered	
April	Return Receipt Showing to Whom, Date, & Addressee's Address	
800	TOTAL Postage & Fees	\$
PS Form 3800 , April 1995	Postmark or Date	

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY		
 Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired. Print your name and address on the reverse so that we can return the card to you. Attach this card to the back of the mailpiece, or on the front if space permits. 	A. Received by (Please Print Clearly) B. Date of Delivery C. Signature Agent Addressee		
1. Article Addressed to: 8 AIRS ID # 0310379001AG JERRY BUSSELL XOMED SURGICAL PRODUCTS	D. Is delivery address different from item 1? ☐ Yes If YES, enter delivery address below: ☐ No		
6743 SOUTHPOINT DRIVE N JACKSONVILLE FL 32216	3. Service Type Certified Mail		
2. Article Number (Copy from service label) 2. 210 663 195			
PS Form 3811, July 1999 Domestic Ret	urn Receipt 102595-99-M-1789		