



Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-5787
847.473.1500

May 8, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, rm. - 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

The undersigned submits this petition under 21 CFR section 5.10, section 10.30, and section 898.14 to request the Commissioner of Food and Drugs to grant a compliance variance with respect to the regulation cited below.

A. ACTION REQUESTED

Pursuant to "The Performance Standard for Electrode Lead Wires and Patient Cables, found in Title 21 CFR, Part 898.12 (a), which was published in the Federal Register on May 9, 1997 [62 FR 25497], "Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3 (c) of the following standard:

International Electrotechnical Commission (IEC)
601-1: Medical Electrical Equipment
601-1 (1988) Part 1: General requirements for safety
Amendment No. 1 (1991)
Amendment No. 2 (1995)

The compliance date with the standard set forth in 898.12(a) is identified at 898.13(a) as May 11, 1998.

However, the "Guidance document on the Performance Standard for Electrode lead Wires and Patient Cables" issued by the Office of Compliance on March 9, 1998 provides that "Manufacturers and users have an additional two years to prepare for implementation of the second phase of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable intended for use with any medical device must comply with the performance standard." Therefore, compliance must have been achieved by May 9, 2000.

Allegiance Healthcare Corporation (Allegiance) is NOT a manufacturer of the types of medical devices covered by 21 CFR Part 898. However, two of the operating units of the Corporation, Allegiance Custom Sterile and our Procedure Based Delivery System Business (PBDS), are engaged in the manufacturer of "Convenience Kits and Trays" and "Procedure Modules". These products are comprised of components, many of which are medical devices themselves, selected by the customer. Allegiance Custom Sterile configures the customer selected components on a tray, wraps and sterilizes the ensemble. The PBDS business performs basically the same operation as Allegiance Custom Sterile with the exception that no further processing, i.e., sterilization is performed.

Beginning in March, 2000 Allegiance began to approach its suppliers of medical devices covered by 21 CFR 898 asking them to identify their compliance status with respect to the pertinent regulation. Of the seven (7) identified suppliers only two (2) responded to our request proactively. Allegiance then proactively called the remaining suppliers with mixed results as to obtaining necessary information.

Allegiance's manufacturer of its convenience Kits and Trays and Procedure Modules containing affected devices was suspended proactively by Allegiance on or about March 22, 2000. All affected devices in our "raw material inventory" are being sent back to their manufacturers. However, even with these proactive measures, Allegiance is still in possession of approximately 750 Kits and Modules which contain devices covered by 21 CFR, part 898. As stated previously, these Kits and Modules were built to fill a specific order of a Customer. Allegiance is providing the Agency with representative examples of the labels from our products to provide an idea of the numbers of components that are contained in the products.

Having identified the scenario of the completed Kits and Modules that Allegiance has on hand, Allegiance respectfully requests that a compliance variance be granted with respect to the effective compliance date of the regulation, identified above as May 9, 2000. Allegiance requests that it be permitted to provide the completed Kits and Modules that it has in its possession to the Customers for which they were prepared and that these Customers be permitted to use the completed products until September 9, 2000.

B. STATEMENT OF GROUNDS

Allegiance respectfully requests this compliance variance due to the fact that despite having employed all possible resources to get completed product to and used by Customers prior to May 9, 2000, this state of events is not going to happen. Allegiance finds itself in possession of hundreds of Kits and Modules that will have to be disassembled and reassembled with the affected component removed. Since additional sterilization may have to be performed, the possibility exists that many components other than those affected by 21 CFR, part 898 will also have to be discarded due to their either not being able to sustain a second sterilization or not being qualified to sustain another sterilization process. These negative impacts will affect Allegiance but they do not begin to account for the negative impact that will be sustained by our Customers who will be deprived of the products they need for their normal operations.

Since Allegiance feels that it has proactively fulfilled its responsibility, especially since it does not manufacture devices subject to 21 CFR, part 898 and since in large part the situation in which it finds itself is beyond its control, the requested compliance variance should be granted.

C. ENVIRONMENTAL IMPACT

Allegiance respectfully requests a categorical exemption concerning Environmental Impact under 21 CFR, part 25.24.

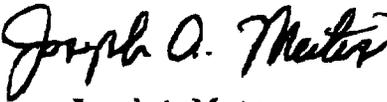
D. ECONOMIC IMPACT

All costs associated with complying with the compliance date identified in the regulation have are not known at this time.

E. CERTIFICATION

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Please direct any additional questions and the Agency's response to the petitioner identified below.

Signature			
Name of Petitioner	Joseph A. Merts		
Mailing Address	Allegiance Healthcare Corporation 1500 Waukegan Road McGaw Park, Illinois 60085		
Fax Number	847-785-2461	Phone Number	847-785-3310

Document Name: untitled

LP00101.3 Cof 3
QFADEV0015 CFRANB

Label Inquiry

06:26:54 5/09/00

Work Order No. 323158
Description.... OPEN HEART PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SCV230HVDP

P/B - "P" Piggy Back

Stat	Part	Qty	Per	Component	Ster Method	Description	P	S	B	A
	01	1.00000		A29154BN	5	DRAPE, CV SPLIT 100x123"				
	01	3.00000		A29350CN	5	DRAPE, 3/4 56x77" REINF				
	01	1.00000		A29468AN	5	DRAPE, FOOT 53x77" ADH				
	01	1.00000		A8188AN	5	CVR, OHT EXT				
	01	1.00000		A8189AN	5	BTC, HVY DTY				
	01	1.00000		A8337CN	5	CVR, MAYO STND				
	01	6.00000		A9015AN	5	GOWN, LG STBK BRETHBL IMP FUL				
	01	3.00000		A9349DN	5	DRAPE, 3/4 57x76" FFLD				
	01	2.00000		A9358DN	5	DRAPE, HALF 44x57" FFLD				
	01	1.00000		CONN285	3	CNCTR, .5x.5" STR				
	01	1.00000		CST-100R	5	TRAY, 2x8.25x10" J-WIRE RECT				
	01	1.00000		DFML	3	PROBE, TEMP MYOCARD 30mm NDL				
	01	1.00000		E2515HNSB	5	PNCL, CTRY RKR SWI BLD HLSTR				+

F3=Exit

F5=Ship Info

F10=Print

F12=Previous

Contents of Pack #1

Date: 5/9/ 0 Time: 07:27:13 AM

Document Name: untitled

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QPADEV0015 CFRANB

Label Inquiry

06:26:54 5/09/00

Work Order No. 323158
Description.... OPEN HEART PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SCV230RVDF

F/B - "F" Piggy Back

Stat Part	Qty Per	Component	Ster Method	Description	P S B A
01	1.00000	E2517H	5	PNCL, CTRY FBTTN BLD 10' REMOV	
01	1.00000	PC400-16	5	CATHR, 16Fr FOLY TEMP SENSR	
01	3.00000	G6B412XR	5	SPNG, 4x8" 12PLY GZE UNIV XRD	
01	5.00000	LS1818SQ	5	SPNG, LAP 18x18" SQ FLD XRD	
01	2.00000	M653G	3	SUT, S25 STEEL 18" MON CCS	
01	20.00000	PWTB003-RAD	5	TWL, 17x27" CTTN FLP BLU RAD	
01	1.00000	RIV-2100B	5	VALVE, SUCT CNTRL L VNT	
01	1.00000	008274	5	CNULA, 34-46Fr VEN TAPR T1969	
01	12.00000	013112-001	5	TIE, CABLE LG LOCKING TBG	
01	2.00000	0935280	5	SYR, BULB 50ml IRR	
01	1.00000	1000008	5	TIP CLNR, CTRY	
01	1.00000	101387-3A	5	INSERT, 86mm TRACTION	
01	1.00000	12325	3	CNULA, 20Fr ART ARCH 6.5mm TIP	+
F3=Exit				F10=Print	F12=Previous
F5=Ship Info					

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LP00101.3 Co# 3
QPADEV0015 CPRANS

Label Inquiry

06:26:54 5/09/00

Work Order No. 323158
Description.... OPEN HEART PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SCV230HVDF

P/B - "P" Piggy Back

Stat Part	Qty Per	Component
01	1.00000	131914003
01	1.00000	14002
01	1.00000	14005
01	1.00000	1560NSLG
01	1.00000	20014NS
01	2.00000	2589-63
01	1.00000	269001
01	2.00000	277935
01	1.00000	30-006
01	1.00000	30001-DLPNS
01	1.00000	301044LF
01	2.00000	301048LF
01	1.00000	301074LF

F3=Exit F5=Ship Info

Star Method	Description	P S B A
3	INSERT, 86MM SMOOTH	
5	MPKR, SKIN VIO REG TIP RLR	
3	CATHR TRAY, 14Fr 22" SUCTGLV	
5	NDL CNTR, 6OCT 2 MAG BLD GD #	
3	CNULA, 14G AORTIC ROOT Y/VMT	
2	SUT, 520 STEEL 24" FEP T5, C86	
3	EO TAPE, .5x4" RED/MAROON	
3	WIRE, PACING ADULT INT INSULA	
5	SPNG, PNT 3/8" FM HLDR XRD	
2	CNULA, 3mm VSSL 2.5" 1WAY	
5	SYR, 20ml LL WO/SHLD	
5	BYR, 60ml LL WO/SHLD	
5	SYR, 3ml LL WO/SHLD	

F10=Print F12=Previous +

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QPADEV0015 CPRANS

Label Inquiry

06:26:54 5/09/00

Work Order No. 323158
Description.... OPEN HEART PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SCV230EVDZ

P/B - "P" Piggy Back

Stat	Part	Qty	Per	Component
01		2.00000		32290-010
01		2.00000		32290-011
01		1.00000		32290-012
01		1.00000		35-3445
01		1.00000		371115
01		2.00000		39S
01		3.00000		3995NS
01		2.00000		41-410
01		1.00000		4800
01		1.00000		SM3228V6
01		1.00000		SSTK15
01		1.00000		S910
01		2.00000		6648F

Stat	Method	Description	P	S	B	A
	5	BLD,#10 STR SURG C-STL				
	5	BLD,#11 STR SURG C-STL				
	5	BLD,#12 STR SURG C-STL				
	5	PUNCH,VASC 4.5mm CLR 7"				
	5	BLD,#15 STR SURG C-STL				
	3	CNCTR,Y 3/8x3/8x3/8"				
	5	STPLR,SKIN 35W				
	5	TRAY,3/4x14x20"				
	5	NET,HEART SUPPORT				
	5	POUCH,STRL VNT 5mil				
	5	BAG,GLASSINE 2.75x3.75" FLAP				
	5	BLD,NDL 3mm CUT EDGE				
	5	DRAPE,IODOPHOR 23.5x35.37FOI				+
		F10-Print				F12=Previous

F3=Exit

F5=Ship Info

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QPADEV0015 CPRANS

Label Inquiry

06:26:54 5/09/00

Work Order No. 323158
Description.... OPEN HEART PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SCV230HVDF

P/B - "P" Piggy Back

Stat Part	Qty Per	Component	Ster Method	Description	P S B A
01	1.00000	6650F	5	DRAPE, IODOPHOR 17.62x35.38FO	
01	1.00000	6651F	5	DRAPE, IODOPHOR 35.38x33.38FO	
01	2.00000	6697D	3	TBC, 9/32" 20' SUCT	
01	2.00000	88-284513	5	TBC, 5mm 1.8m SUCT N/C FNL/FN	
01	2.00000	88-570564	5	CATHR, 36FY THOR 20" STR 6EVE	
01	1.00000	88-571059	5	CATHR, 32FY THOR 20" R/A 6EVE	
01	2.00000	9034870	5	YANKR, BLB TIP WO/CNTRL VNT C	
01	1.00000	950-804B	5	SPNG, STK FLAT 1.5" GZE XRD	
01	2.00000	9606-48	5	STCKNT, 6"x4' 2PLY	
01	1.00000	9999	3	SUCKER, 13" INTRACARD RGD ANG	

F3=Exit

F5=Ship Info

F10=Print

F12=Previous

Pack #1

Document Name: uncitled

00401.03 3 Convertors/Custom Sterile - Charlotte 7:36:58 5/09/00
 WDEV0003 Label Print - Inquiry CSMPRB

Work Order No. 350917
 Description... MAYFIELD OPEN HEART PACK
 Start - "W" Run Without "D" Deleted

Catalog Number SCV22MFBAG
 P/B - "P" Piggy Back

Kit Part	Qty Per	Component	Ster Method	Description	P B	S A
1	1.00000	A8152AN	5	C,HVY DTY		
1	1.00000	A8385	5	C,HVY DTY ISO.BAC/REINF		
1	1.00000	A9446BN	5	APE, LG 72x85"		
1	2.00000	CK092	5	IP, LIGAT SS MD/LG 6 EXTRA		
1	3.00000	CST-30R	5	AY, 2x4.75x9" ORGANIZER		
1	1.00000	E1450GNSB	5	ELECTRODE, BLD 2.75" COATED		
1	5.00000	FG71-2482	5	THR, 22Pp URETH RED RBR		
1	1.00000	MCS20	3	DO, STPLR #20 SM 9-1/8"		
1	2.00000	MSM20	3	DO, STPLR #20 SM 9-1/8" Ti		
1	2.00000	MX431-1L	3	PCK, 3-WAY SNGL M LL		
1	1.00000	PCP40	3	EDGT, PTFE 1/16x3/16x3/8" SOFT		
1	2.00000	PS2009	6	G, 5x7" 2mil		
1	1.00000	P1NS	5	KR, SKIN VIO		

More...

F12=Return

F10=Print

F5=Ship Info

F1=Exit

Contents of Pack #2

Document Name: untitled

LP00401.03 3 Convertors/Custom Sterile - Charlotte 7:36:58 5/09/00
QPADEV0003 Label Print - Inquiry CSMFRB

Work Order No. 350917
Description... MAYFIELD OPEN HEART PACK Catalog Number SCV22MPBAG
Stat - "W" Run Without "D" Deleted P/B - "P" Piggy Back

Kit Part	Qty Per	Component	Star Method	Description	P B	S A
1	1.00000	W31G	3	X,BONE 2.5g		
1	.05200	YR3051	3	PE,PAPER 2"x36yd LO-TACWHI		
1	1.00000	0075	5	L,BLANK STD WHI		
1	2.00000	0077	5	L,PAPAVERINE STD BLK/WHI		
1	1.00000	01031	5	L,HEPARIN STD BLK/WRI		
1	2.00000	01079	5	L,SALINE STD BLK/WHI		
1	3.00000	0198	5	L,HEPARIN W/SALINE STD BK/WH		
1	1.00000	03055	5	L,LATEX ITEMS STD BLK/WHI		
1	1.00000	0402	5	L,CARDIOPLEGIA STD BLK/WHI		
1	1.00000	1000008	5	P CLMR,CTRY		
1	1.00000	11009010	3	CKER,13" INTRACARD RGD ANG		
1	2.00000	1260NSLG	5	L CNTR,60CT 2 MAG RED #S		
1	4.00000	15204-00X	3	R,35ml REG LUER		

F3=Exit

F5=Ship Info

F10=Print

MORE...
F12=Return

Pack #2

Document Name: untitled

LP00401.03 3 Convertors/Custom Sterile - Charlotte 7:36:58 5/09/00
 QPADEV0003 Label Print - Inquiry CSMPRB

Work Order No. 350917
 Description.... MAYFIELD OPEN HEART PACK Catalog Number SCV22MFBAG
 Stat - "W" Run Without "D" Deleted P/B - "P" Piggy Back

Kit Part	Qty Per	Component	Ster Method	Description	P S B A
1	1.00000	2C5627	3	T,IV EXT 35" M WO/CLMP	
1	1.00000	200433	5	L,25Gx1.25" RED AL HUB	
1	1.00000	26350-810	5	G,8x10" 2mil	
1	2.00000	301036LF	5	R,60ml LS W/SHLD	
1	1.00000	301043LF	5	R,10ml LS WO/SHLD	
1	1.00000	301087LF	5	R,3ml LS WO/SHLD	
1	1.00000	303010	5	L,25Gx5/8" REG BLU PLAS HUB	
1	1.00000	304134LF	3	R,CNTRL 10ml LL W/SHLD L/F	
1	1.00000	31-1827NS	3	L,18G 7cm PUNCT NO WINGS	
1	4.00000	32290-010	5	D,#10 STR SURG C-STL	
1	2.00000	32290-011	5	D,#11 STR SURG C-STL	
1	1.00000	32290-021	5	D,#21 STR SURG C-STL	
1	2.00000	371115	5	D,#15 STR SURG C-STL	

F3=Exit

F5=Ship Info

F10=Print

More...
 F12=Return

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LP00401.03 3 Convertora/Custom Sterile - Charlotte 7:36:58 5/09/00
 QPADEV0003 Label Print - Inquiry CSMPRB

Work Order No. 350917
 Description.... MAYFIELD OPEN HEART PACK Catalog Number SCV22MFBAG
 Stat - "W" Run Without "D" Deleted P/B - "P" Piggy Back

Kit Part	Qty Per	Component	Ster Method	Description	P B	S A
1	1.00000	381123	3	THR,22GX1" IV BLE		
1	1.00000	381267	5	THR,14GX1.75" IV ORANGE		
1	1.00000	390-0541	5	AY,5x4x1" BLUE QUARTR SHALLO		
1	1.00000	4456	3	THR,20GX1.25" IV MTL HB		
1	.60000	492020	5	THR,10Fr ROB RED 16"FNLTFR		
1	1.00000	5M322BV6	5	UCH,STRL VNT 5ml		
1	3.00000	5STK15	5	G,GLASSINE 2.75x3.75" FLAP		
1	1.00000	54555	5	BLE,6' SURG EXT ALLIG CLIP		
1	1.00000	65-2017	5	AY,MAYO 13x19"		
1	1.00000	79466	3	APE,CV INCISE 80x108x126"		
1	1.00000	9034870	5	NKR,BLB TIP WO/CNTRL VNT CLR		
1	2.00000	950-427B	5	NG,PNT 3/8" FM HLDR XRD		

F3=Exit F5=Ship Info F10=Print Bottom F12=Return

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LP00101.3 Co# 3
QPADEV0015 CPRANB

Label Inquiry

06:23:18 5/09/00

Work Order No. 323508
Description.... FACEMAKER PBDS PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SAN21PCBRE

P/B - "P" Piggy Back

Stat	Part	Qty	Per	Component	Star Method	Description	P/B	Back
							P	S
							B	A
01		1.00000		A29420CN	5	DRAPE, CHEST/BRPAS 100X122X77		
01		1.00000		A4024	5	CSR, BIO-SHLD II		
01		1.00000		A4467AN	3	SCRUB TRAY, SKIN PVP-I GEL		
01		1.00000		A8184BN	5	BTC, UNFOLDED		
01		2.00000		AB520BN	5	TWL, ABS WHI		
01		4.00000		AB554DN	5	TWL, 17x26" N-ABS ADH		
01		2.00000		A9041AN	5	GOWN, XL STBK BRETHBL IMP SLV		
01		1.00000		BF5127	5	NDL, 25Gx1.5" REG BLU		
01		1.00000		CPI-9040LF	5	BANDBAG, 26" DEEP CLR LTX/FRE		
01		1.00000		CST-30R	5	TRAY, 2x4.75x9" ORGANIZER		
01		4.00000		PWTB003-RAD	5	TWL, 17x27" CTTN FLF BLU RAD		
01		1.00000		10390-010	5	BAG, BEDSIDE PAPER		
01		1.00000		130319	5	PNCL, CTRY RKR SWI HLSTR BLD		+
F3=Exit				F5=Ship Info	F10=Print		F12=Previous	

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Date: 5/9/0 Time: 07:23:31 AM

Document Name: untitled

Label Inquiry

06:23:18 5/09/00

LP00101.3 Cof 3
QPADEV0015 CPRANB

Work Order No. 323508
Description.... PACEMAKER FBDS PACK
Stat - "W" Run Without "D" Deleted

Catalog Number SAN21PCBRE

P/B - "P" Piggy Back

Stat	Part	Qty Per	Component	Ster Method	Description	P S B A
	01	1.00000	301042LF	5	SYR,10ml LL WO/SHLD	
	01	1.00000	301043LF	5	SYR,10ml LS WO/SHLD	
	01	1.00000	5M2024V6	5	POUCH,STRL VNT 5mil	
	01	1.00000	5159	5	NPL,22Gx1.5" NYPO SHRT BVL	
	01	1.00000	5455B	5	CABLE,6' SURG EXT ALLIG CLIP	
	01	1.00000	7148	5	SPNG,4x4" 16PLY GZE BND XRD	

F3=Exit

F5=Ship Info

F10=Print

F12=Previous

Pack #3

Date: 5/9/ 0 Time: 07:23:35 AM



*Allegiance Healthcare Corporation
1500 Waukegan Road
McGraw Park, Minnetonka 55045-6787
847.473.1500
FAX: 847.785.2451*

May 24, 2000

Mr. Stewart Crumpler
Office of Compliance
US FDA
Rockville, Maryland

Re: Citizen Petition concerning compliance to the Electrode Lead Wire Standard

Dear Mr. Crumpler:

Pursuant to our telephone conversation this morning I would like to provide you with the following additional information regarding our Citizen Petition dated May 8, 2000.

1. The Petition identifies "Convenience Kits and Trays" and "Procedure Modules". Convenience Kits and Trays are products coming out of our Allegiance Custom Sterile business. The Kits and Trays are comprised of various "components", some of which may be medical devices in and of themselves, selected by the Customer and arranged on a tray by Allegiance. The assembled tray is then further processed, i.e., sterilized by Allegiance rendering the entire ensemble sterile.

The Procedure Modules are products coming out of our Allegiance Procedure Based Delivery System (PBDS) business. The Procedure Modules are comprised once again of "components", some of which may be medical devices, selected by the Customer. In this instance the Modules, as an ensemble, are not further processed, i.e., sterilized by Allegiance. They may, however, contain sterile items that were sterilized by their manufacturers and which are packaged in their own sterile packaging. The Procedure Modules may contain all of the items that a patient may need for a particular hospital stay from bathrobe and slippers to complicated medical devices. For example, a Convenience Kit may be included in a Procedure Module as a component.

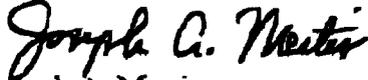
2. The total number of completed Kits and Trays and Modules presently at our Facilities is approximately 750. Of this number approximately 650 are sterile Kits and Trays. The remaining, approximately 100, are Procedure Modules that, although completed, are non sterile. As explained, there may be some sterile components in these completed Procedure Modules.

Understanding from our discussion, the fact that the requirement for reesterilization may be the justification for granting the requested compliance variance, it may be appropriate, as a rationale, to grant the variance solely to those products that would require reesterilization after the effected electrode, for example, is removed. If this scenario were adopted the 650 Kits and Trays coming out of Allegiance Custom Sterile would be exempted because all would require reesterilization and possibly some of the Allegiance PBDS Modules, those that may contain an effected electrode in a sterile Kit, would be under the variance.

Please do not hesitate to contact me again, if further information is required.

We sincerely appreciate your assistance in this matter.

Respectfully,



Joseph A. Mertis
Director, Regulatory Affairs