

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

5716 '00 MAY -8 P1:19

## CITIZEN PETITION

The undersigned submits this petition under the provisions of § 21 CFR 898.14 (a) of the Performance Standard for Electrode Lead Wires and Patient Cables to request the Commissioner of Food and Drugs to refrain from taking enforcement action for a period of 90 days after the compliance date mandated in § 21 CFR 898.13 (b) of May 9, 2000.

### *Action Requested*

The undersigned requests that the Commissioner of Food and Drugs refrain from taking enforcement or any other form of administration action for a period of 90 days after the May 9, 2000 compliance date mandated in § 21 CFR 898.13 (b). This request for relief from compliance with § 21 CFR 898.12 Performance Standard for Electrode Lead Wires and Patient Cables refers specifically to § 21 CFR 898.12 (a) "Any connector in a cable of 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)" and

"(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3 (c) of the standard set forth in paragraph (a) of this section."

The undersigned manufactures and markets electrophysiology catheters, extension cables, electrophysiology recording and stimulation equipment. These products fall under the requirements of the § 21 CFR 898.12 Performance Standard.

### *Statement of Grounds*

The undersigned has been actively working towards compliance with § 21 CFR 898.12, the Performance Standard for Electrode Lead Wires and Patient Cables. Although a large portion of equipment and devices have been converted, everything is not expected to be converted by the May 9, 2000 compliance date required by § 21 CFR 898.13 (b). This delay is the direct result of our raw material vendors' inability to deliver new compliant

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connectors on time due to the current high demand for these scarce parts. Our vendor for these connectors is Multi Contact, a company based in Sweden. The distributor in the United States is Kensington.

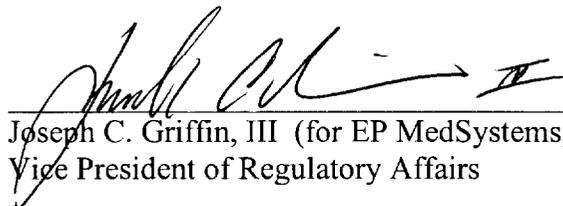
Adapters are available but can be easily removed and therefore would not comply with the requirements of IEC 601-1. The cost of employing a means to permanently mount adapters to our equipment would be greater than replacing the equipment with new compliant connectors. We are currently offering our customers an exchange for new equipment.

If we are unable to continue to supply customers with these products for the short grace period beyond the compliance date requested, patients may go untreated and we stand to suffer financial loss as well. Also, of even more concern, we uncovered from a telephone survey of end users, that hospitals, although aware of the new standard, will not have all equipment and devices converted by the compliance date. If this situation is as wide spread as it seems throughout the Country, product shortages will result and physicians may be forced to use products illegally.

We agree with the need for the Performance Standard for Electrode Lead Wires and Patient Cables to increase patient safety. However, electrophysiology is a highly specialized branch of cardiology where exposed 2mm pin contacts have been in use for over 30 years. Given the fact that both industry and practitioners are aware of the new Performance Standard and compliance is close at hand, we believe that an additional 90 days past the May 9, 2000 compliance date for electrophysiology type device use does not pose an imminent safety risk to the patient.

### *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.

  
\_\_\_\_\_  
Joseph C. Griffin, III (for EP MedSystems, Inc.)  
Vice President of Regulatory Affairs

4-26-00  
Date

EP MedSystems, Inc.  
100 Stierli Court, Suite 107  
Mt. Arlington, NJ 07856

Tel. 1-973-398-2800  
Fax 1-973-398-8636

# EP MedSystems

Cooper Run Executive Park  
575 Route 73 North, Building D  
West Berlin, NJ 08091



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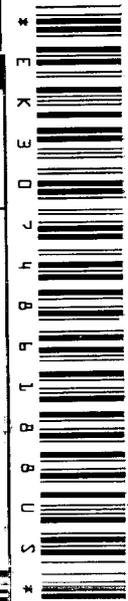
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