



## DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42/EEC

# VARIAN

Certificate Number: M5-0140

medical systems

This declaration is hereby made under Annex II of the Council Directive concerning Medical Devices; 93/42/EEC of June 14th 1993. Medical Devices covered by this declaration comply with the provisions of Council Directive 93/42/EEC which apply to them.

### NOTIFIED BODY

The British Standards Institution have been appointed to undertake activities pursuant to Annex II in respect of all devices except those Class I devices supplied non-sterile and which do not have a measuring function.

### REFERENCED STANDARDS/NORMATIVE DOCUMENTS

EN ISO 13485:2003, EN ISO 14971:2007, EN ISO 10993-1:2009, EN ISO 10993-5:2009, EN ISO 11737-1:2006, EN ISO17665-1:2006, EN ISO 17664:2004, EN 980:2008, EN 1041:2008, EN 62366:2008

### PRODUCT/PRODUCT GROUP

#### 3 Channel Applicators:

GM11000730 Fletcher Style Applicator Set - Flexible Geometry      GM11000810 Fletcher Style Applicator - Defined Geometry  
GM11006200 Titanium Fletcher-style Applicator Set - Defined Geometry      GM11006860 Titanium Fletcher Style Applicator Set - Flexible Geometry  
GM11006940 Manchester-style Applicator Set - Flexible Geometry      AL13030001 Titanium Fletcher-Suit-Delclos-style Applicator Set - Flexible Geometry  
GM11010320 Sterilization Box for Fletcher-style Applicators-Defined Geometry.

### LEGAL MANUFACTURER:

Varian Medical Systems, Inc.  
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Palo Alto, CA 94304-1038, USA  
tel: +1 650 493 4000  
[www.varian.com](http://www.varian.com)

### CLASSIFICATION

93/42/EEC Annex IX Device Classification:  
All 3 Channel Applicators, Class IIa, Rule 5.  
GM11010320 Sterilization Box, Class 1, Rule 1

### EUROPEAN REPRESENTATIVE:

Varian Medical Systems UK Limited  
Gatwick Road  
Crawley  
West Sussex  
RH10 9RG

### INTERNATIONAL SUBMISSIONS DOSSIER (TECHNICAL FILE REFERENCE)

3-Channel Applicators  
ISD: 09-012 Rev 6

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