# DECLARATION OF CONFORMITY WITH DIRECTIVE93/42/EEC

VARIAN
medical systems

**Certificate Number:** M5-0008

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 60601-1:1990/ A1:1993/A2:1995
EN 60601-1-4: 1996/A1:1999
EN 60601-1-2:2001/ A1:2006
EN 60601-2-1:1998/A1:2002
IEC 61217:1996 +A1:2000
EN 60601-1-6:2004
ISO 13485: 2003
ISO 14971:2007
BS EN 1041:2008
BS EN 980:2008

**PRODUCT/PRODUCT GROUP**

***Varian High-Energy Linear Accelerator:***

Trilogy, Novalis Tx
Clinac iX, Clinac Cx
Trilogy Tx
Clinac 2100C, 2100 C/D, 2300 C/D
Clinac 21 EX, 23 EX
Clinac DHX, DMX

**LEGAL MANUFACTURER:**
Varian Medical Systems, Inc.
3100 Hansen Way
Palo Alto, CA 94304-1038, USA
tel: +1 650 493 4000
www.varian.com

**CLASSIFICATION**
93/42/EEC Annex IX Device Classification: IIb
Rule 9

**INTERNATIONAL SUBMISSIONS DOSSIER (TECHNICAL FILE REFERENCE)**
High-Energy Linear Accelerator
**ISD:** 09-011

**EUROPEAN REPRESENTATIVE:**
Varian Medical Systems UK Limited
Gatwick Road
Crawley
West Sussex
RH10 9RG

**AUTHORIZED:** Sara Muddell **TITLE:** International Corporate Regulatory Affairs Manager **DATE:** 12 March 2010