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 functio

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Reason: MoldSign Signature
Location:

REFERENCED STANDARDS/NORMATIVE DOCUMENTS

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

PRODUCT/PRODUCT GROUP

Varian High-Energy Linear Accelerator:

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