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DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42/EEC

VARIAN
medical systems

Certificate Number: *M5-0180*

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 60601-1-1: 2001
EN 60601-1-2:2001
EN 60601-1-4:1996
IEC 60601-2-17:2004
EN 62366:2008

PRODUCT/PRODUCT GROUP

GammaMed*plus* iX / GammaMed*plus* 3/24 iX

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)

GammaMedplus iX
ISD: 10-007 Issue 5

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

AUTHORIZED: Sara Muddell **TITLE:** International Corporate Regulatory Affairs Manager **DATE:** 05 OCTOBER 2012

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