CE 2797

DECLARATION OF CONFORMITY WITH DIRECTIVE 93/42/EEC

varian

Certificate Number: M5-0561 **EC Certificate Number:** CE 01414

This declaration is hereby made under the responsibility of the legal manufacturer. Medical Devices covered by this declaration comply with the provisions of:

- Council Directive 93/42/EEC on Medical Devices

NOTIFIED BODY

The British Standards Institution have been appointed to undertake activities pursuant to Annex II of Council Directive 93/42/EEC 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 60601-1:2006
EN 60601-1-2:2007
IEC 60601-2-1:2009 + A1:2014
EN 61217:2012
EN 62304:2006
EN 62366:2008
EN 60601-1-6:2010
ISO 13485:2016
EN ISO 14971:2012
BS EN 1041:2008
EN ISO 15223-1:2016

Digitally signed by Chicu Natalia
Date: 2022.08.09 16:08:11 EEST
Reason: MoldSign Signature
Location: Moldova

PRODUCT/PRODUCT GROUP

Varian High Energy Linear Acclerator

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

CLASSIFICATION

93/42/EEC Annex IX Device Classification: IIb, Rule 9
GMDN: 35159; Linear Accelerator System

INTERNATIONAL SUBMISSIONS DOSSIER (TECHNICAL FILE REFERENCE)

ISD: Varian High Energy Linear Accelerator, ISD 12-009

LEGAL MANUFACTURER:
Varian Medical Systems, Inc.
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Palo Alto, CA 94304-1038, USA

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TITLE: Director, Regulatory Affairs

SIGNED: Sara Muddell

DATE: 15 MARCH 2019

This Declaration of Conformity is valid until the expiration date of EC Certificate referenced above.
Format: L2447 Rev 04