



Declaration of Conformity With Directive 93/42/EEC



Product Name:	AlignRT Plus
Alternative / Additional Names for Marketing:	Optical Surface Monitoring System (OSMS), Gate CT, GateRT, AlignRT SRS Module, AlignRT Offline
Manufacturer's Name:	Vision RT Limited
Manufacturer's Address:	Dove House Arcadia Avenue London N3 2JU United Kingdom
Manufacturing Address:	Jays Close Basingstoke Hampshire RG22 4BS United Kingdom

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

GMDN Code: 47816

GMDN Description: Video camera patient positioning/tracking system

Product Description

AlignRT Plus is a video-based three-dimensional (3D) surface imaging system, which is used to image the skin surface of a patient in 3D before and during radiotherapy treatment.

Referenced Standards

EN ISO 13485:2012+AC2012	EN 60601-1:2006+A11:2011 +A1:2013
EN 1041:2008+A1:2013	EN 60601-1-2:2007+AC 2010
EN 980:2008	EN 60950-1:2006+A12:2011*
EN ISO 15223-1:2012*EN ISO 15223-2:2010*	EN 60825-1:2014*
EN ISO 14971:2012	EN ISO 10993-1:2009 + AC:2010
EN 62366:2008	EN 62471:2008*
EN 62304:2006 + A1-2015	EN 61217:2012

*Denotes a standard that is not Harmonised to the Directive.

Notified Body

The British Standards Institute (BSI) have been appointed to undertake activities pursuant to Annex II in respect of all devices. BSI Certificate CE 95048 first issued 13 July 2005.

Classification 93/42/EEC Annex IX Device Classification: IIb (Rule 9)

Declaration of Conformity Authorized By:

Chris Hannan

(Name)

VP of Quality & Regulatory Affairs

(Job Title)

(Date)

DocuSigned by:

Chris Hannan

Signer Name: Chris Hannan
Signing Reason: I approve this document
Signing Time: 7/6/2018 8:12:44 AM BST

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(Signature)