

**EC DECLARATION OF CONFORMITY**

1) Manufacturer (Name, department): **Codonics, Incorporated**

Address: **17991 Englewood Drive, Middleburg Heights, Ohio 44130. USA**

and

2) European authorized representative: **CEpartner4U BV**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS Tel.: +31 (0)6 516 536 26;

3) Product(s) (name, type or model/batch number, etc.):

**Image Printers, Servers, and accessories / recording media, see Appendix**

4) The product(s) described above is in conformity with:

<u>Title</u>	<u>Document No.</u>
<b>Medical Device Directive</b>	93/42/EEC
<b>Restriction of the use of certain hazardous substances (RoHS)</b>	2011/65/EU

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: Medical Device Directive, Annex VII

Middleburg Heights, Ohio

July 1, 2014



**Alan DeSantis, VP, Regulatory Affairs and QA**

ORIGINAL ON FILE WITH

CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands. Tel.: +31 (0)6.516.536.26; or as:

## Appendix

Date: 2014-04-15

List of Devices

DEVICE NAME	MODEL	RISKCLASS / RULE	First Date of CE Marking
Horizon-xx CNFG 2. xx or higher IEC 60601-1 3 <sup>rd</sup> Ed.	Ci, Ci-RAD, Ci-s, GS, G1, G2, GS-RAD, GS-s, SF, G, & XL Long Film Imager	Class 1-Rule 12 (Image printer)	03/13/2002
D6000 Disinfection Technology	6Xi and variant(s)	Class 1-Rule 12 Disinfection Device	06/1/2014
LifImager-XX CNFG 8.xx or higher		Class 1-Rule 12 (Image printer)	06/17/2004
GE Medical Multi-media Imager-XX CNFG 8.xx or higher IEC 60601-1 3 <sup>rd</sup> Ed	Models included: Ci, GS, SF, XL Long Film Imager	Class 1-Rule 12 (Image printer)	07/11/2007
iCRco iFilm CReator CNFG 8.xx or higher	iCRco iFilm CReator	Class 1-Rule 12 (Image printer)	08/23/2007
PROImager-XX: part 4120-9-0001 PROImager-XX-plus: part 4120-9-0003 CNFG 8.xx or higher	PROImager	Class 1-Rule 12 (Image printer)	07/11/2007 07/11/2007
Virtua Medical CD/DVD Disc Publisher IEC 60601-1 3 <sup>rd</sup> Ed Virtua XR Medical CD/DVD Disc Publisher IEC 60601-1 3 <sup>rd</sup> Ed INTEGRITY Medical Disc Importer INFINITY Medical Image Server	Virtua, Virtua C,  Virtua E, Virtua XR  LX	Class 1- Rule 12  (Medical Image Data Storage Device) Device- Class 1 Device- Class 1	06/27/2006  07/11/2007 02/28/2008 02/03/2009
Safe Labeling System SLS Safe Label System Administrative Tool IEC 60601-1 3 <sup>rd</sup> Ed	SLS-500i, SLS-500P PC Software	Class 1- Rule 12 (Medication Data Management Device)	03/03/2011 03/03/2011
DAYLIGHT Modality Print Solution	PC Software	Class 1- Rule 12 (Medical Image Data Storage Device)	03/03/2011

DEVICE NAME	MODEL	RISKCLASS / RULE	First Date of CE Marking
Various sizes of DVC/DVB (Radiographic Film) and DVP, CVP (listed as Color and Gray Scale White Films), CVT/CVF (Transparency Color Films) Sizes included: A, A4, 8x10, 11x14, 14x17, and 14x36, 14x51	Direct Vista Blue & Clear film Direct Vista Paper  Chroma Vista Paper Chroma Vista Transparency and/or Chroma Vista Film DirectVista Long Film	Class 1-Rule 1 (Hardcopy Media)	05/14/2003   06/17/2004 06/17/2004 02/15/2007
Lifelmager media of Various sizes of DVC/DVB (Radiographic Film) and DVP, CVP (listed as Color and Gray Scale White Films), CVT/CVF (Transparency Color Films)	Lifelmager DVB&DVC Blue film Lifelmager DVP Paper Lifelmager CVP Paper Life Imager CVF Transparency and/or Film	Class 1-Rule 1 (Hardcopy Media)	06/17/2004  06/17/2004 06/17/2004 06/17/2004
PROImager-XX Medical Imaging Film	PROImager DVB 14x17 and 8x10 (Radiographic Film)	Class 1-Rule 1 (Hardcopy Media)	07/11/2007
GE Medical Imaging Film Various sizes of DVC/DVB (Radiographic Film) and DVP, CVP (listed as Color and Gray Scale White Films), CVT/CVF (Transparency Color Films) Sizes included: A, A4, 8x10, 11x14, 14x17, and 14x36, 14x51	8" x 10", 14" x 17" ( blue and clear) Medical Imaging Film DVB/DVC A4, 14" x 17" Medical Imaging Grayscale Paper DVP A4 Medical Imaging Colour Paper CVP	Class 1-Rule 1 (Hardcopy Media)	07/11/2007
iCRco Medical Imaging Film	iCRco iFilm CReator DVB 14x17 and 8x10 (Radiographic Film)	Class 1-Rule 1 (Hardcopy Media)	08/23/2007

**Note:**

\* Lifelmager Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for Ferrania UK Ltd

\* PROTEC Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for PROTEC Medical Systems

\* GE Healthcare Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for GE Healthcare

\* iCRco iFilm Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged for iCRco Incorporated

Product ALIAS CROSS REFERENCE		Codonics Integrity		Codonics Infinity LX		Codonics Infinity Raw Data Storage Server	
Image Importer/Viewer		GCQ VIEW1 Image Station				<u>Codonics Infinity-1 or Codonics Raw Data Storage System Unit (Infinity-1 RDSS)</u>	
Image Storage Server		Siemens SRD				Toshiba RDSS (CRRS-010A/2B)	
IMAGERS ALIAS CROSS REFERENCE	Codonics Horizon Ci	Codonics Horizon GS (1114)	Codonics Horizon GS	Codonics Horizon G (1417/810)	Codonics Horizon SF	Codonics Horizon XL LONG FILM	
Imagers/Media	Lifemager 6050	Lifemager 6021	Lifemager 6024	Lifemager 6010			
				Protec E Protec E PLUS iCRco iFilm CReator			
	GE Multi-media IMAGER Ci		GE Multi-media Imager GS		GE Multi-media Imager SF	GE Multi-media Imager XL	

<b>DirectVista</b>					
	<b>Film</b>				
<b>Blue 1417-DVB</b>	Lifemager DVB		Lifemager DVB	Lifemager DVB PROTEC Medical Imaging Film DVB iCRco iFilm CReator DVB	
	GE Medical Imaging Film DVB		GE Medical Imaging Film DVB		
<b>Blue 1114-DVB</b>	Lifemager DVB	Lifemager DVB			
<b>Blue 810-DVB</b>	Lifemager DVB GE Medical Imaging Film DVB	Lifemager DVB	Lifemager DVB GE Medical Imaging Film DVB		GE Medical Imaging Film DVB
				iCRco iFilm CReator DVB PROTEC Medical Imaging Film DVB	
<b>Blue 1436-DVB</b>					GE Medical Imaging Film DVB
<b>Blue 1451-DVB</b>					GE Medical Imaging Film DVB

<b>White Film</b>					
<b>1417-DVP</b>	Lifemager DVP GE Medical Imaging Grayscale Paper DVP		GE Medical Imaging Grayscale Paper DVP		GE Medical Imaging Grayscale Paper DVP
<b>A4-DVP</b>	Lifemager DVP GE Medical Imaging Grayscale Paper DVP	Lifemager DVP	Lifemager DVP GE Medical Imaging Grayscale Paper DVP	GE Medical Imaging Grayscale Paper DVP	GE Medical Imaging Grayscale Paper DVP

**ChromaVista**
**White Film**

<b>A4-CVP</b>	Lifemager CVP
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**Transparency**GE Medical  
Imaging Colour  
Paper CVPGE Medical  
Imaging Colour  
Paper CVPGE Medical  
Imaging Colour  
Paper CVP

A4-CVT/CVF

Lifelmager CVF