

**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
LifelImager-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
LifelImager 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)	LifelImager DVB&DVC Blue film  LifelImager DVP Paper LifelImager 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:**

\* LifelImager 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



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Product ALIAS CROSS REFERENCE	Codonics Integrity	Codonics Infinity LX	Codonics Infinity Raw Data Storage Server
Image Importer/Viewer	GCQ VIEW1 Image Station		Codonics Infinity-1 or Codonics Raw Data Storage System Unit (Infinity-1 RDSS)
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 SF	GE Multi-media Imager XL
	GE Multi-media IMAGER Ci		GE Multi-media Imager GS			

DirectVista						
Film						
Blue 1417-DVB	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			
Blue 1114-DVB	Lifemager DVB	Lifemager DVB				
Blue 810-DVB	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		
Blue 1436-DVB						GE Medical Imaging Film DVB
Blue 1451-DVB						GE Medical Imaging Film DVB

White Film						
1417-DVP	Lifemager DVP GE Medical Imaging Grayscale Paper DVP		GE Medical Imaging Grayscale Paper DVP			GE Medical Imaging Grayscale Paper DVP
A4-DVP	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						
A4-CVP	Lifemager CVP					



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**Transparency**  
GE Medical  
Imaging Colour  
Paper CVP

GE Medical  
Imaging Colour  
Paper CVP

GE Medical  
Imaging Colour  
Paper CVP

A4-CVT/CVF

Lifemager CVF