

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>
Medical Device Directive	93/42/EEC
Restriction of the use of certain hazardous substances (RoHS)	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 rd 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 rd 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 rd Ed Virtua XR Medical CD/DVD Disc Publisher IEC 60601-1 3 rd 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 rd 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

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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TransparencyGE Medical
Imaging Colour
Paper CVPGE Medical
Imaging Colour
Paper CVPGE Medical
Imaging Colour
Paper CVP

A4-CVT/CVF

Lifelmager CVF