



Declaration of Conformity	Document ref.: TF/ 1
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EC DECLARATION OF CONFORMITY

1) **Manufacturer:** **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 device labels printed as:

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

or as: CEpartner4U, 3951DB; 13. NL. tel: +31 (0)6.516.536.26)

3) **Product(s):**
Image Printers and accessories / recording media, per exhibit A (page 2 of 3 attached)

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

<u>Document No.</u>	<u>Title</u>	<u>Edition / Date of issue</u>
L 169; 93/42/EEC	Medical Device Directive	1993-06-14

5) **Additional information**

Conformity assessment procedure for CE marking-

Medical Device Directive, Annex VII.

Middleburg Heights, Ohio

JUNE 28, 2006

Date of issue in USA

Codonics, Inc,

Alan DeSantis, Director Regulatory Affairs and QA

Maarn, NL

June 28, 2006

Date of issue in NL

CEpartner4U BV, Harry Teirlinck, Senior Consultant

ORIGINAL ON FILE WITH

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

CEpartner4U, 3951DB; 13. NL. tel: +31 (0)6.516.536.26)

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CODONICS	Date: 06/27/06	Page: 2
ID	Description	First registration
EP-1660Lx-x Revision code xxxx-xxx-xx-Exx or higher	Class 1-Image printer	04/08/2001
Horizon-xx CNFG 2. xx or higher Models included: CI, CI-s, GS, GS-s, SF, G, & XL Long Film Imager	Class 1-Image printer	03/13/2002
NP/EP-1600-xx Revision code xxxx-xxx-xx-Exx or higher	Class 1-Image printer	05/14/2003
EP-1650-xx Revision code xxxx-xxx-xx-Exx or higher	Class 1-Image printer	05/14/2003
NP/EP-1660-xx Revision code xxxx-xxx-xx-Exx or higher	Class 1-Image printer	05/14/2003
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	05/14/2003 06/17/2004 06/17/2004
Virtua Medical CD/DVD Disc Publisher	Medical Image Data Storage Device	06/27/2006
Lifemager-XX CNFG 8.xx or higher	Class 1-Image printer	06/17/04
Lifemager 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)	Lifemager DVB or DVC Blue film Lifemager DVP Paper Lifemager CVP Paper Life Imager CVF Transparency and/or Film	06/17/2004 06/17/2004 06/17/2004 06/17/2004
<i>*Lifemager Products are Horizon imagers and media manufactured by Codonics and Labeled/Packaged for Ferrania UK Ltd</i>		

Medical Device Directive 93/42/EEC:

- Encompasses EN 60601-1-2 and
- EN 60601-1-2 Class B

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IMAGERS ALIAS CROSS REFERENCE	Codonica Horizon CI	Codonica Horizon GS (1114)	Codonica Horizon GS	Codonica Horizon G(1417)
Imagers/Media	Lifemager 6050	Lifemager 6021	Lifemager 6024	Lifemager 6010
DirectVista				
Film				
Blue 14x17 DVB	Lifemager DVB		Lifemager DVB	Lifemager DVB
Blue 11x14 DVB	Lifemager DVB	Lifemager DVB		
Blue 8x10 DVB	Lifemager DVB	Lifemager DVB	Lifemager DVB	
White Film				
14x17 DVP	Lifemager DVP			
A4 DVP	Lifemager DVP	Lifemager DVP	Lifemager DVP	
ChromaVista				
White Film				
A4 CVP	Lifemager CVP			
Transparency				
A4 CVT/CVF	Lifemager CVF			