

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 |
| 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 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 |
| 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