



## DECLARATION OF CONFORMITY

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

Address: **17991 Englewood Drive, Middleburg Heights, Ohio 44130. USA**  
SRN: **US-MF-000008190**

2) European authorized representative for MDR and RoHS

**C e p a r t n e r 4 U**

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

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS [www.cepartner4u.com/](http://www.cepartner4u.com/)

SRN: **NL-AR-000000111**

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

**Image Printers, Disc Publishers, Medication Safety Systems, and  
accessories / Film (image recording media)**

*See appendix*

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

| <u>Title</u>                                                                    | <u>Document No.</u>                      |
|---------------------------------------------------------------------------------|------------------------------------------|
| <b>Medical Device Regulation</b>                                                | <b>(EU) 2017/745</b>                     |
| <b>Restriction of the use of certain<br/>hazardous substances (RoHS)</b>        | <b>2011/65/EU and 2015/863/EU</b>        |
| <b>Registration, Evaluation, and<br/>Authorization of Chemicals<br/>(REACH)</b> | <b>1907/2006/EU</b>                      |
| <b>ISO 13485:2016/NS-EN ISO<br/>13485:2016</b>                                  | <b>245216-2017-AQ-USA-NA-PS Rev. 1.0</b> |
| <b>IEC 60601-1-2:2014 4th Edition</b>                                           | <b>(EU) 2017/745</b>                     |

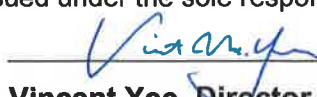
5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure: Medical Device Regulation: Art. 19, Annex II, III and IV

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Middleburg Heights, Ohio

October 25, 2021

  
**Vincent Yee, Director Regulatory Affairs and QA**

**CODONICS**

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## Appendix

Date: 2021-10-25

### List of devices.

| Product name        | Trade name                                                                                    | Product code / catalogue number / unambiguous ref. | Intended purpose                     | Risk class / rule <sup>1</sup> | Basic UDI-DI <sup>2</sup> GMN              | First date of CE-compliance            |
|---------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------|--------------------------------|--------------------------------------------|----------------------------------------|
| <b>MEDICAL FILM</b> | DirectVista Medical Film, Models DVB, DVC, DVBT, DVB5, sizes 8x10, 11x14, 14x17, 14x36, 14x51 | GMDN 63183<br>CND Z130106                          | Diagnostic Procedure Hardcopy Images | I, Rule 1                      | See appendix UDI PAGE 081490502DVCVHCM014Y | 05/14/2003<br>06/20/2016<br>11/15/2019 |
|                     | ChromaVista White Film, Models DVP, CVP, sizes A, A4, 11x14, 14x17                            | CND Z130190<br>(Various)CND<br>Z13019099 (Other)   |                                      |                                |                                            |                                        |
|                     | Direct Vista Blue & Clear film                                                                |                                                    |                                      |                                |                                            |                                        |
|                     | Direct Vista Blue-5                                                                           |                                                    |                                      |                                |                                            |                                        |
|                     | Direct Vista Blue-T Base                                                                      |                                                    |                                      |                                |                                            |                                        |
|                     | Direct Vista Paper, Direct Vista White Film (A, A4, 810, 1114, 1417)                          |                                                    |                                      |                                |                                            |                                        |
|                     | Chroma Vista Paper, Chroma Vista White Film                                                   |                                                    |                                      |                                |                                            |                                        |
|                     | Chroma Vista Transparency and/or Chroma Vista Film (A, A4)                                    |                                                    |                                      |                                |                                            | 06/17/2004                             |
|                     | DirectVista Long Film (1436, 1451)                                                            |                                                    |                                      |                                |                                            | 02/15/2007                             |

<sup>1</sup> See risk classification in Medical Device Regulation, annex VIII

<sup>2</sup> Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability is provided by the Basic UDI-DI



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|                                  |                                                                                            |                             |                                                             |                   |                                              |                          |
|----------------------------------|--------------------------------------------------------------------------------------------|-----------------------------|-------------------------------------------------------------|-------------------|----------------------------------------------|--------------------------|
| <b>IMAGERS</b>                   | Horizon Medical Multimedia Dry<br>Imagers                                                  | GMDN 36782/<br>CND Z110706  | Diagnostic<br>Procedure<br>Image Printing                   | I, Rule 1 &<br>13 | See appendix UDI PAGE<br>081490502HZMMI01G9  | 03/13/2002               |
|                                  | <b>CI</b> Large Format Color, Gray Scale,<br>Film                                          |                             |                                                             |                   |                                              |                          |
|                                  | <b>GS</b> Large Format Gray Scale                                                          |                             |                                                             |                   |                                              |                          |
|                                  | <b>SF</b> Small Format Color, Gray Scale,<br>Film                                          |                             |                                                             |                   |                                              |                          |
|                                  | <b>G</b> (1417) Three Input Single Media                                                   |                             |                                                             |                   |                                              |                          |
| <b>Medication<br/>Management</b> | <b>G1</b> Single Input Multi Format, Gray<br>Scale, Film                                   |                             |                                                             |                   |                                              |                          |
|                                  | <b>G2</b> Dual Input Multi Format, Gray<br>Scale, Film                                     |                             |                                                             |                   |                                              |                          |
|                                  | <b>XL</b> Medical Long Film Imager (1436<br>& 1451)                                        |                             |                                                             |                   |                                              |                          |
|                                  | Safe Label System SLS 500i/550ii<br>Point of Care Station (PCS)                            | GMDN 37588<br>CND A0704     | Medication<br>Preparation and<br>Label Printing             | I, Rule 1 &<br>13 | See appendix UDI PAGE<br>081490502SLSPCS01XR | 03/03/2011               |
|                                  | Virtua Medical Image Disc<br>Publisher, Models<br>Virtua, Virtua XR, Virtus E,<br>Virtua C | GMDN 64454<br>CND Z11069099 | Diagnostic<br>Image Disc<br>Recording and<br>Label Printing | I, Rule 1 &<br>13 | See appendix UDI PAGE<br>081490502VRMDP01KK  | 06/27/2006<br>07/11/2007 |



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#### APPENDIX UDI REFERENCE

| MODEL NAME                                         |                  | DESCRIPTION                                                                             | UDI-DI                             |
|----------------------------------------------------|------------------|-----------------------------------------------------------------------------------------|------------------------------------|
| <b>IMAGERS</b>                                     |                  | <b><u>HORIZON MULTIMEDIA IMAGERS</u></b>                                                | <b><u>081490502HZMMI01G9</u></b>   |
| <b>Base Model</b>                                  | <b>HZMMI01</b>   |                                                                                         |                                    |
|                                                    |                  | <b><u>*BOLD PACKAGE/CASE LEVEL</u></b>                                                  |                                    |
|                                                    |                  | <b><u>UNBOLD UNIT/SYSTEM LEVEL</u></b>                                                  |                                    |
| Codonics Horizon® Ci Multi-media Imager            |                  | Grayscale/Color Desktop Large Format Film and Paper Diagnostic Imager                   | 00814905020076                     |
| Codonics Horizon® G1 Multi-media Imager            |                  | Grayscale Desktop Large Format Film and Paper Diagnostic Imager, 1 Media Input          | 00814905020083                     |
| Codonics Horizon® G2 Multi-media Imager            |                  | Grayscale Desktop Large Format Film and Paper Diagnostic Imager, 2 Media Input          | 00814905020090                     |
| Codonics Horizon® GS Multi-media Imager            |                  | Codonics Grayscale Desktop Large Format Film and Paper Diagnostic Imager, 3 Media Input | 00814905020106                     |
| Codonics Horizon® SF Multi-media Imager            |                  | Grayscale/Color Desktop Small Format Film and Paper Diagnostic Imager                   | 00814905020113                     |
| Codonics Horizon® XL Multi-media Imager            |                  | Grayscale/Color Desktop XL Format Film and Paper Diagnostic Imager                      | 00814905020120                     |
|                                                    |                  |                                                                                         |                                    |
| <b>FILM</b>                                        |                  | <b><u>DirectVista ChromaVista Hardcopy</u></b>                                          | <b><u>081490502DVCVHCM014Y</u></b> |
| <b>BASE MODEL</b>                                  | <b>DVCVHCM01</b> | <b><u>Medical Media</u></b>                                                             |                                    |
|                                                    |                  |                                                                                         |                                    |
| Codonics DirectVista Thermal Film, 1417-DVB        |                  | 1417-DVB Blue Base Film (100 sheet cassette)                                            | 00814905020601                     |
| <b>Codonics DirectVista Thermal Film, 1417-DVB</b> |                  | <b>1417-DVB Blue Base Film (500 sheets/5 cassette case)</b>                             | <b>10814905020608</b>              |
| Codonics DirectVista Thermal Film, 1417-DVC        |                  | 1417-DVC Clear Base Film (100 sheet cassette)                                           | 00814905020618                     |
| <b>Codonics DirectVista Thermal Film, 1417-DVC</b> |                  | <b>1417-DVC Clear Base Film (500 sheets/5 cassette case)</b>                            | <b>10814905020615</b>              |
| Codonics DirectVista Thermal Film, 1114-DVB        |                  | 1114-DVB Blue Base Film (100 sheet cassette)                                            | 00814905020625                     |



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|                                                     |                                                              |                       |
|-----------------------------------------------------|--------------------------------------------------------------|-----------------------|
| <b>Codonics DirectVista Thermal Film, 1114-DVB</b>  | <b>1114-DVB Blue Base Film (500 sheets/5 cassette case)</b>  | <b>10814905020622</b> |
| Codonics DirectVista Thermal Film, 810-DVB          | 810-DVB Blue Base Film (100 sheet cassette)                  | 00814905020632        |
| <b>Codonics DirectVista Thermal Film, 810-DVB</b>   | <b>810-DVB Blue Base Film (500 sheets/5 cassette case)</b>   | <b>10814905020639</b> |
| Codonics DirectVista Thermal Film, 810-DVC          | 810-DVC Clear Base Film (100 sheet cassette)                 | 00814905020649        |
| <b>Codonics DirectVista Thermal Film, 810-DVC</b>   | <b>810-DVC Clear Base Film (500 sheets/5 cassette case)</b>  | <b>10814905020646</b> |
| Codonics DirectVista Thermal Film, 810-DVB          | 810-DVB Blue Base Film (100 sheet boxed)                     | 00814905021042        |
| <b>Codonics DirectVista Thermal Film, 810-DVB</b>   | <b>810-DVB Blue Base Film (500 sheets/5 boxes case)</b>      | <b>10814905021049</b> |
| Codonics DirectVista Thermal Film, 810-DVC          | 810-DVC Clear Base Film (100 sheet box)                      | 00814905021059        |
| <b>Codonics DirectVista Thermal Film, 810-DVC</b>   | <b>810-DVC Clear Base Film (500 sheets/5 boxed case)</b>     | <b>10814905021056</b> |
| Codonics DirectVista Thermal Film, 1436-DVB         | 1436-DVB Blue Base Film (25 sheet cassette)                  | 00814905020656        |
| Codonics DirectVista Thermal Film, 1451-DVB         | 1451-DVB Blue Base Film (25 sheet cassette)                  | 00814905020663        |
| <b>Codonics DirectVista Thermal Film, 1436-DVB</b>  | <b>1436-DVB Blue Base Film (100 sheets/4 cassette case)</b>  | <b>10814905020653</b> |
| <b>Codonics DirectVista Thermal Film, 1451-DVB</b>  | <b>1451-DVB Blue Base Film (100 sheets/4 cassette case)</b>  | <b>10814905020660</b> |
| Codonics DirectVista Thermal Film, 1417-DVBT        | 1417-DVBT Blue Base Film (100 sheet cassette)                | 00814905020670        |
| <b>Codonics DirectVista Thermal Film, 1417-DVBT</b> | <b>1417-DVBT Blue Base Film (500 sheets/5 cassette case)</b> | <b>10814905020677</b> |
| Codonics DirectVista Thermal Film, 810-DVBT         | 810-DVBT Blue Base Film (100 sheet cassette)                 | 00814905020687        |
| <b>Codonics DirectVista Thermal Film, 810-DVBT</b>  | <b>810-DVBT Blue Base Film (500 sheets/5 cassette case)</b>  | <b>10814905020684</b> |
| Codonics DirectVista Paper/White Film, A-DVP        | A-DVP White Base Film, (80 sheet cassette)                   | 00814905020694        |
| <b>Codonics DirectVista Paper/White Film, A-DVP</b> | <b>A-DVP White Base Film, (400 sheets/5 cassette case)</b>   | <b>10814905020691</b> |



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|                                                        |                                                               |                       |
|--------------------------------------------------------|---------------------------------------------------------------|-----------------------|
| Codonics DirectVista Paper/White Film, A4-DVP          | A4-DVP White Base Film, (80 sheet cassette)                   | 00814905020700        |
| <b>Codonics DirectVista Paper/White Film, A4-DVP</b>   | <b>A4-DVP White Base Film, (400 sheets/5 cassette case)</b>   | <b>10814905020707</b> |
| Codonics DirectVista Paper/White Film, 1417-DVP        | 1417-DVP White Base Film, (80 sheet cassette)                 | 00814905020717        |
| <b>Codonics DirectVista Paper/White Film, 1417-DVP</b> | <b>1417-DVP White Base Film, (400 sheets/5 cassette case)</b> | <b>10814905020714</b> |
| Codonics DirectVista Paper/White Film, 1114-DVP        | 1114-DVP White Base Film, (80 sheet cassette)                 | 00814905020724        |
| <b>Codonics DirectVista Paper/White Film, 1114-DVP</b> | <b>1114-DVP White Base Film, (400 sheets/5 cassette case)</b> | <b>10814905020721</b> |
| Codonics ChromaVista Paper/WhiteFilm, A-CVP            | A-CVP White Base Film, (50 sheet cassette)                    | 00814905020731        |
| <b>Codonics ChromaVista Paper/WhiteFilm, A-CVP</b>     | <b>A-CVP White Base Film, (100 sheets/2 cassette case)</b>    | <b>10814905020738</b> |
| Codonics ChromaVista Paper/WhiteFilm, A4-CVP           | A4-CVP White Base Film, (50 sheet cassette)                   | 00814905020748        |
| <b>Codonics ChromaVista Paper/WhiteFilm, A4-CVP</b>    | <b>A4-CVP White Base Film, (100 sheets/2 cassette case)</b>   | <b>10814905020745</b> |
| Codonics DirectVista Thermal Film, 1417-DVB5           | 1417-DVB5 Blue Base Film (100 sheet box)                      | 00814905020885        |
| <b>Codonics DirectVista Thermal Film, 1417-DVB5</b>    | <b>1417-DVB5 Blue Base Film (500 sheets/5 box case)</b>       | <b>10814905020882</b> |
| Codonics DirectVista Thermal Film, 1114-DVB5           | 1114-DVB5 Blue Base Film (100 sheet box)                      | 00814905020892        |
| <b>Codonics DirectVista Thermal Film, 1114-DVB5</b>    | <b>1114-DVB5 Blue Base Film (500 sheets/5 box case)</b>       | <b>10814905020899</b> |
| Codonics DirectVista Thermal Film, 810-DVB5            | 810-DVB5 Blue Base Film (100 sheet box)                       | 00814905020908        |
| <b>Codonics DirectVista Thermal Film, 810-DVB5</b>     | <b>810-DVB5 Blue Base Film (500 sheets/5 box case)</b>        | <b>10814905020905</b> |
| Codonics DirectVista Thermal Film, 1417-DVB5           | 1417-DVB5 Blue Base Film (100 sheet cassette)                 | 00814905020915        |
| <b>Codonics DirectVista Thermal Film, 1417-DVB5</b>    | <b>1417-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>  | <b>10814905020912</b> |
| Codonics DirectVista Thermal Film, 1114-DVB5           | 1114-DVB5 Blue Base Film (100 sheet cassette)                 | 00814905020922        |



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|                                                             |                                                                                                                                    |                                   |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <b>Codonics DirectVista Thermal Film, 1114-DVB5</b>         | <b>1114-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>                                                                       | <b>10814905020929</b>             |
| Codonics DirectVista Thermal Film, 810-DVB5                 | 810-DVB5 Blue Base Film (100 sheet cassette)                                                                                       | 00814905020939                    |
| <b>Codonics DirectVista Thermal Film, 810-DVB5</b>          | <b>810-DVB5 Blue Base Film (500 sheets/5 cassette case)</b>                                                                        | <b>10814905020936</b>             |
| Codonics DirectVista Thermal Film, 1436-DVB5                | 1436-DVB5 Blue Base Film (25 sheet cassette)                                                                                       | 00814905020946                    |
| <b>Codonics DirectVista Thermal Film, 1436-DVB5</b>         | <b>1436-DVB5 Blue Base Film (100 sheets/4 cassette case)</b>                                                                       | <b>10814905020943</b>             |
| Codonics DirectVista Thermal Film, 1451-DVB5                | 1451-DVB5 Blue Base Film (25 sheet cassette)                                                                                       | 00814905020953                    |
| <b>Codonics DirectVista Thermal Film, 1451-DVB5</b>         | <b>1451-DVB5 Blue Base Film (100 sheets/4 cassette case)</b>                                                                       | <b>10814905020950</b>             |
| <b><u>DISC PUBLISHERS</u></b>                               | <b><u>Virtua Medical Disc Publisher</u></b>                                                                                        | <b><u>081490502VRMDP01KK</u></b>  |
| <b><u>BASE MODEL</u></b>                                    | <b><u>VRMDP01</u></b>                                                                                                              |                                   |
| Codonics Virtua® Medical Disc Publisher                     | Integrated Virtua DICOM Server & Medical Disc (CD/DVD) Publisher System                                                            | 00814905020328                    |
| Codonics Virtua® XR Medical Disc Publisher                  | Integrated Virtua XR DICOM Server & Medical Disc (CD/DVD) Publisher System                                                         | 00814905020335                    |
| Codonics Virtua® C and E Medical Disc Publisher             | Integrated Virtua C DICOM Server & Medical Disc (CD/DVD) Publisher System                                                          | 00814905020359                    |
| <b><u>MEDICATION LABEL SYSTEM</u></b>                       | <b><u>SAFE LABEL SYSTEM POINT of CARE SYSTEM</u></b>                                                                               | <b><u>081490502SLSPCS01XR</u></b> |
| <b><u>BASE MODEL</u></b>                                    |                                                                                                                                    |                                   |
| <b><u>SLSPCS01</u></b>                                      |                                                                                                                                    |                                   |
| Codonics Safe Label System®(SLS) 500i Point of Care Station | Integrated computer-based barcode scan & print system automatically to verify drugs & print labels of prepared drugs & other items | 00814905020229                    |
| Codonics Safe Label System®(SLS) 550i Point of Care Station | Integrated computer-based barcode scan & print system automatically to verify drugs & print labels of prepared drugs & other items | 00814905020366                    |



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**Product ALIAS CROSS  
REFERENCE**

Note:

\* SRM Products are Horizon imagers and media manufactured by Codonics and Labelled /Packaged  
for SRM Romania

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

| DEVICE NAME | MODEL | RISKCLASS / RULE | First Date of CE Marking |
|-------------|-------|------------------|--------------------------|
|-------------|-------|------------------|--------------------------|

SRM Medical imager G2 part HRG2T-SRM-01  
SRM Medical imager Gs part HRGsT-SRM-02 CNFG 8.xx or higher

SRM Imager

I, Rule 1 & 13 (Image printer) 06/17/2019 (MDD)

SRM media of Various sizes of DVC/DVB/DVBT/DVB5 (Radiographic Film)

SRM 8"x10", 11"x14",  
14"x17" Medical Imaging  
Film

I, Rule 1 (Hardcopy Media) 06/17/2019 (MDD)

| IMAGERS ALIAS<br>CROSS REFERENCE  | Codonics<br>Horizon Ci         | Codonics<br>Horizon G2      | Codonics<br>Horizon GS                                     | Codonics<br>Horizon G<br>(1417/810) | Codonics<br>Horizon SF            | Codonics Horizon XL LONG FILM |
|-----------------------------------|--------------------------------|-----------------------------|------------------------------------------------------------|-------------------------------------|-----------------------------------|-------------------------------|
| Imagers/Media                     | GE Multi-media<br>IMAGER Ci    | SRM Medical<br>imager G2    | SRM Medical<br>imager GS<br>GE Multi-media<br>Imager GS    |                                     | GE Multi-media &<br>OEC Imager SF | GE Multi-media Imager XL      |
| DirectVista Film<br>Blue 1417-DVB | GE Medical<br>Imaging Film DVB | SRM Medical<br>Imaging Film | SRM Medical<br>Imaging Film<br>SRM Medical<br>Imaging Film |                                     |                                   |                               |



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## Blue 1114-DVB

### Blue 810-DVB

SRM Medical  
Imaging Film  
GE Medical  
Imaging Film DVB

SRM Medical  
Imaging Film

SRM Medical  
Imaging Film  
GE Medical  
Imaging Film DVB

GE Medical  
Imaging Film DVB

Codonics DirectVista  
Thermal Film, 810-  
DVB

Codonics DirectVista  
Thermal Film, 810-  
DVB

Codonics DirectVista  
Thermal Film, 810-  
DVC

Codonics DirectVista  
Thermal Film, 810-  
DVC

OEC Boxed Film

810-DVB Blue Base  
Film (100 sheet  
boxed)

810-DVB Blue Base  
Film (500 sheets/5  
boxes case)

810-DVC Clear Base  
Film (100 sheet box)

810-DVC Clear Base  
Film (500 sheets/5  
boxed case)

## Blue 1436-DVB

## Blue 1451-DVB

GE Medical Imaging Film DVB  
GE Medical Imaging Film DVB

## White Film

### 1417-DVP

GE Medical  
Imaging Grayscale  
Paper DVP

GE Medical  
Imaging Grayscale  
Paper DVP

GE Medical Imaging Grayscale Paper DVP

## White Film

### A4-DVP

GE Medical  
Imaging Grayscale  
Paper DVP

GE Medical  
Imaging Grayscale  
Paper DVP

GE Medical Imaging Grayscale Paper DVP