



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



Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS 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>
Medical Device Regulation	(EU) 2017/745
Restriction of the use of certain hazardous substances (RoHS)	2011/65/EU and 2015/863/EU
Registration, Evaluation, and Authorization of Chemicals (REACH)	1907/2006/EU
ISO 13485:2016/NS-EN ISO 13485:2016	245216-2017-AQ-USA-NA-PS Rev. 1.0
IEC 60601-1-2:2014 4th Edition	(EU) 2017/745

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



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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 ¹	Basic UDI-DI ² GMN	First date of CE-compliance
MEDICAL FILM	DirectVista Medical Film, Models DVB, DVC, DVBT, DVB5, sizes 8x10, 11x14, 14x17, 14x36, 14x51 ChromaVista White Film, Models DVP, CVP, sizes A, A4, 11x14, 14x17 Direct Vista Blue & Clear film Direct Vista Blue-5 Direct Vista Blue-T Base Direct Vista Paper, Direct Vista White Film (A, A4, 8,10, 11,14, 14,17) Chroma Vista Paper, Chroma Vista White Film Chroma Vista Transparency and/or Chroma Vista Film (A, A4) DirectVista Long Film (1436, 1451)	GMDN 63183 CND Z130106 CND Z130190 (Various)CND Z13019099 (Other)	Diagnostic Procedure Hardcopy Images	I, Rule 1	See appendix UDI PAGE 081490502DVCVHMC014Y	05/14/2003 06/20/2016 11/15/2019 06/17/2004 06/17/2004 06/17/2004 02/15/2007

¹ See risk classification in Medical Device Regulation, annex VIII

² 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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IMAGERS	Horizon Medical Multimedia Dry Imagers Ci Large Format Color, Gray Scale, Film GS Large Format Gray Scale SF Small Format Color, Gray Scale, Film G (1417) Three Input Single Media G1 Single Input Multi Format, Gray Scale, Film G2 Dual Input Multi Format, Gray Scale, Film XL Medical Long Film Imager (1436 & 1451)	GMDN 36782/ CND Z110706	Diagnostic Procedure Image Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502HZMMI01G9	03/13/2002
Medication Management	Safe Label System SLS 500i/550ii Point of Care Station (PCS)	GMDN 37588 CND A0704	Medication Preparation and Label Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502SLSPCS01XR	03/03/2011
Medical Disc Recorders	Virtua Medical Image Disc Publisher, Models Virtua, Virtua XR, Virtua E, Virtua C	GMDN 64454 CND Z11069099	Diagnostic Image Disc Recording and Label Printing	I, Rule 1 & 13	See appendix UDI PAGE 081490502VRMDP01KK	06/27/2006 07/11/2007



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APPENDIX UDI REFERENCE

MODEL NAME		DESCRIPTION	UDI-DI
IMAGERS		HORIZON MULTIMEDIA IMAGERS	081490502HZMMI01G9
Base Model	HZMMI01	*BOLD PACKAGE/CASE LEVEL UNBOLD UNIT/SYSTEM LEVEL	
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
FILM			
BASE MODEL	DVCVHCM01	DirectVista ChromaVista Hardcopy Medical Media	081490502DVCVHCM014Y
Codonics DirectVista Thermal Film, 1417-DVB		1417-DVB Blue Base Film (100 sheet cassette)	00814905020601
Codonics DirectVista Thermal Film, 1417-DVB		1417-DVB Blue Base Film (500 sheets/5 cassette case)	10814905020608
Codonics DirectVista Thermal Film, 1417-DVC		1417-DVC Clear Base Film (100 sheet cassette)	00814905020618
Codonics DirectVista Thermal Film, 1417-DVC		1417-DVC Clear Base Film (500 sheets/5 cassette case)	10814905020615
Codonics DirectVista Thermal Film, 1114-DVB		1114-DVB Blue Base Film (100 sheet cassette)	00814905020625



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



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



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Codonics DirectVista Thermal Film, 1114-DVB5	1114-DVB5 Blue Base Film (500 sheets/5 cassette case)	10814905020929
Codonics DirectVista Thermal Film, 810-DVB5	810-DVB5 Blue Base Film (100 sheet cassette)	00814905020939
Codonics DirectVista Thermal Film, 810-DVB5	810-DVB5 Blue Base Film (500 sheets/5 cassette case)	10814905020936
Codonics DirectVista Thermal Film, 1436-DVB5	1436-DVB5 Blue Base Film (25 sheet cassette)	00814905020946
Codonics DirectVista Thermal Film, 1436-DVB5	1436-DVB5 Blue Base Film (100 sheets/4 cassette case)	10814905020943
Codonics DirectVista Thermal Film, 1451-DVB5	1451-DVB5 Blue Base Film (25 sheet cassette)	00814905020953
Codonics DirectVista Thermal Film, 1451-DVB5	1451-DVB5 Blue Base Film (100 sheets/4 cassette case)	10814905020950
<u>DISC PUBLISHERS</u>	<u>Virtua Medical Disc Publisher</u>	<u>081490502VRMDP01KK</u>
<u>BASE MODEL</u>		
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
<u>MEDICATION LABEL SYSTEM</u>	<u>SAFE LABEL SYSTEM POINT OF CARE SYSTEM</u>	<u>081490502SLSPCS01XR</u>
<u>BASE MODEL</u>		
<u>SLSPCS01</u>		
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
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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 CROSS REFERENCE	Codonics Horizon Ci	Codonics Horizon G2	Codonics Horizon GS	Codonics Horizon G (1417/810)	Codonics Horizon SF	Codonics Horizon XL LONG FILM
Imagers/Media	SRM Medical imager G2 GE Multi-media IMAGER Ci	SRM Medical imager G2	SRM Medical imager GS GE Multi-media Imager GS	SRM Medical imager GS GE Multi-media Imager GS	GE Multi-media & OEC Imager SF	GE Multi-media Imager XL
DirectVista Film						
Blue 1417-DVB	SRM Medical Imaging Film GE Medical Imaging Film DVB	SRM Medical Imaging Film	SRM Medical Imaging Film SRM Medical Imaging Film	SRM Medical Imaging Film SRM Medical Imaging Film	GE Medical Imaging Film	GE Medical Imaging Film DVB

