

Authorized Representative Declaration

This is to declare that, in accordance with the Medical Device Regulation (EU) 2017/745, **CEpartner4U BV** will perform all duties and accept all responsibilities as

Authorized Representative

SRN: NL-AR-000000111

mandated for following devices:

Device group	EMDN	Registration	Risk class
Imagers	Z110706	Registration in EUDAMED	I
Medical film	Z130106	Registration in EUDAMED	I
Medical Disc recorders	Z11069002	Registration in EUDAMED	I
Medication Management	A0704	Registration in EUDAMED	I

of

Codonics Inc.

17991 Englewood Drive
Middleburg Heights, Ohio 44130
United States

SRN: US-MF-000008190

as agreed upon in Agreement: ARMD/01-Q106.12C
(signed 21 June 2001), as amended

The manufacturer has provided CEpartner4U with documentation attesting compliance with the requirements under (EU) 2017/745.

Issue date: 16 May 2025

Expiry: subject to a recurrent requirement, which should be addressed every 12 months.



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ce partner 4U

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1) **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) Registration, Evaluation, and Authorization of Chemicals (REACH)	2011/65/EU and 2015/863/EU 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

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

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

3) **UDI/EUDAMED REFERENCE**

<u>MODEL NAME</u>	<u>DESCRIPTION</u>	<u>UDI-DI</u>
<u>IMAGERS</u> <u>Base Model</u> <u>HZMMI01</u>	<u>HORIZON MULTIMEDIA</u> <u>IMAGERS</u>	<u>081490502HZMMI01G9</u>
	<u>*BOLD PACKAGE/CASE</u> <u>LEVEL</u>	
	<u>UNBOLD UNIT/SYSTEM</u> <u>LEVEL</u>	
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
<u>FILM</u> <u>BASE MODEL</u> <u>DVCVHCM01</u>	<u>DirectVista ChromaVista</u> <u>Hardcopy Medical Media</u>	<u>081490502DVCVHCM014Y</u>
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
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
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
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>BASE MODEL</u> <u>VRMDP01</u>	<u>Virtua Medical Disc</u> <u>Publisher</u>	<u>081490502VRMDP01KK</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 BASE MODEL SLSPCS01</u>	<u>SAFE LABEL SYSTEM POINT of CARE SYSTEM</u>	<u>081490502SLSPCS01XR</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
Codonics Safe Label System®(SLS) 600i Point of Care Station	Integrated computer-based barcode scan & print system automatically to verify drugs & print labels of prepared drugs & other items	00814905021103