

Technical Documentation

Title: Device and Package Labels

Device name: iVAC 2L

Types: LV16 and LV17

MDR Reference: Annex II – Chapter 2

IMDRF RowID: 5.02

Revision: 7

Document status: Final

Date current revision: 01-jun.-26

Sign-off

	Author	Reviewer
Name & Function:	Bastiaan Vliegenthart QA/RA Manager	Rindu Hoeksema Quality Engineer

Date:	27-mei-26	27-mei-26
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Signature:		<i>Rindu Hoeksema</i>
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Approval by Technical Team

Name & Function:	Marc Klinkhamer Vice President QA/RA	Oren Malchin CEO
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Date:	01-jun.-26	01-jun.-26
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Signature:	 Marc pulsecath (1 jun. 2026 15:10:40 GMT+2)	 Oren Malkin (1 jun. 2026 15:12:14 GMT+2)
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Device and Package Labels (LV16 and LV17)

The iVAC 2L devices contain multiple labels in the form of stickers.

The box of the iVAC 2L devices contain the main product label. Each functional component of the iVAC 2L contains its own label on its sterile packaging.

The labels contain internationally recognised symbols according to EN ISO 15223-1:2021.

The next table lists the label filename for each part number. Refer to the attachments for an example of each label.

For the LV17 Version 3G, the following labels apply (see attachments):

Label description	Valid Label Revision*
PulseCath iVAC 2L (17 Fr.) – Label on outer packaging box	PulseCath L iVAC 2L 17Fr-4
LV17 catheter with insertion set – Part 17081	PulseCath L 17081CE-0
Membrane Pump – Part 21009	PulseCath L 21009CE-6
Catheter Protector – Part 17022	PulseCath L 17022CE-4
Extra PTFE Catheter Inner Tube – Part 17075	PulseCath L 17075CE-0

For the LV16 type, the following labels apply (see attachments):

Label description	Valid Label Revision*
PulseCath iVAC 2L (16 Fr.) – Label on outer packaging box	PulseCath L iVAC 2L 16Fr-0
LV16 catheter with insertion set – Part 16081	PulseCath L 16081CE-0
Membrane Pump – Part 21009	PulseCath L 21009CE-6
Catheter Protector – Part 17022	PulseCath L 17022CE-4
Extra PTFE Catheter Inner Tube – Part 17075	PulseCath L 17075CE-0

For the LV17 Version 3F, the following labels apply (see attachments):

Label description	Valid Label Revision*
PulseCath iVAC 2L (17 Fr.) – Label on outer packaging box	PulseCath L iVAC 2L 17Fr-4
LV17 catheter with insertion set – Part 17037	PulseCath L 17037CE-4
Membrane Pump – Part 21009	PulseCath L 21009CE-6
Catheter Protector – Part 17022	PulseCath L 17022CE-4
Extra PTFE Catheter Inner Tube – Part 17062	PulseCath L 17062CE-5

*The last number of the filename of the Label indicates the revision.

Note that the LOT number of the iVAC 2L devices are composed of the following:

1. number 3 for the LV17 type or number 7 for LV16 type
2. one letter and
3. five numbers.

Note that the LOT number of components is composed of the following:

1. the part number,
2. two letters and
3. two numbers.

UDI carrier (LV16 and LV17)

A unique UDI has been assigned to both types of the iVAC 2L. The UDI carrier is located on the label of the box as shown in attachment 1 and 3.¹

The coding standards from GS1 are used for the UDI carrier. Both the Device Identifier (UDI-DI) and Product Identifier (UDI-PI) are concatenated in a single GS1-128 barcode to allow automatic identification and data capture (AIDC). The Human Readable Interpretation (HRI) is located underneath the barcode. The UDI contains UDI-PIs for expiration date and lot number.

The iVAC 2L has only one packaging level where packaging level is defined as the level of device packaging that contains a defined quantity of devices; in case of the iVAC 2L this is the box.

No unique UDI has been assigned to the individual components of the iVAC 2L, because these components are not considered devices on their own and are not commercially available. Nor are they part of a configurable device that is marked with its own UDI.

Attachments

Attachment 1: PulseCath L iVAC 2L 17Fr-4

Attachment 2: PulseCath L 17081CE-0

Attachment 3: PulseCath L 17037CE-4

Attachment 4: PulseCath L iVAC 2L 16Fr-0

Attachment 5: PulseCath L 16081CE-0

Attachment 6: PulseCath L 21009CE-6

Attachment 7: PulseCath L 17022CE-4

Attachment 8: PulseCath L 17062CE-5

Attachment 9: PulseCath L 17075CE-0

References

EN ISO 15223-1:2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

Revision history

Revision 7: Changed PulseCath L 16037CE-0 to PulseCath L 16081CE-0. Both labels are the same apart from the lot numbering. Editorial corrections.

Revision 6: Added LV17 Version 3G to the scope. Added labels L 17075CE-0 and L 17081CE-0.

Revision 5: Added type designation on front page to indicate which device type of the iVAC 2L this document covers. Marked which sections apply to which type(s) of the device.

¹ The UDI-DI and UDI-PI in the example label of attachment 1 is subject to change. Refer to TD A2 1.1-Device Description and Specification for the current UDI-PI of each device type and version.

Revision 4: Added labels for the 16Fr variant of the iVAC 2L. Changed address from Arnhem to Breukelen on all labels resulting in the following revised labels: L iVAC 2L 17Fr-4, L 17037CE-4, PulseCath L 21009CE-6, L 17022CE-4 and L 17062CE-5. The labels for the 16Fr components immediately get the updated address.

Revision 3: Removed regional labels from TD.

Revision 2: Revised PulseCath L iVAC 2L 17Fr to revision 3 to which the UDI symbol was added and protective packaging symbol was added to the STERILE symbol. Added section on UDI carrier. Added section on regional labels and attachment 6. Moved the example of the additional label for Thailand to Attachment 6.

Revision 1: Lot number example text provided in such a way that it is unambiguous, and cannot be mistaken for the part number. Changed the description text in PulseCath L 17062CE from "PTFE Insertion Tubing" to "Extra PTFE Catheter inner tube" to align with the IFU. Added specific text for products to be distributed to Thailand to PulseCath L iVAC 2L 17Fr. Updated illustration in PulseCath L iVAC 2L 17Fr to specify the diameter of the flexible catheter part and the tip accurately. Note: PulseCath L iVAC 2L 17Fr went from rev 0 to rev 2. Rev 1 is used within the Design Dossier of the iVAC 2L compliant to the Medical Device Directive.

Revision 0: new document. Reason: refresh of the iVAC 2L Design Dossier (DD LV17 7-5 Labelling, compliant to the Medical Device Directive 93/42/EEC) to the Technical Documentation requirements of the Medical Device Regulation (EU) 2017/745 and alignment with the International Medical Device Regulators Forum (IMDRF) table of contents format for regulatory submission.

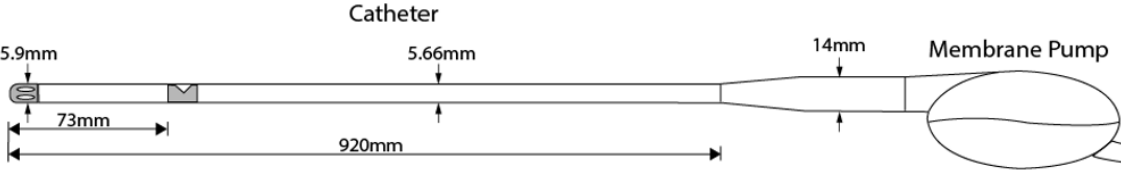
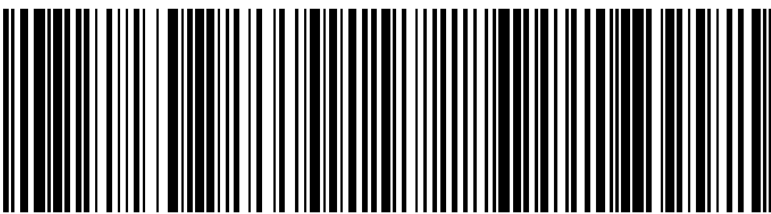
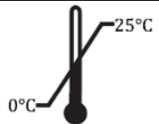
Changes to the legacy document "DD LV17 7-5 Labelling":

To labels L 17037CE-3, L 21009CE-4, L 17022CE-2, L 17062CE-1 the following was changed: Added symbol for date of manufacture with year and month and added symbol for single sterile barrier system. Replaced general warning symbol for do not resterilise and symbol for do not use if package is damaged. Replaced the words "Manufactured by:" with the symbol for manufacturer.

No changes are made to L iVAC 2L 17Fr-0.

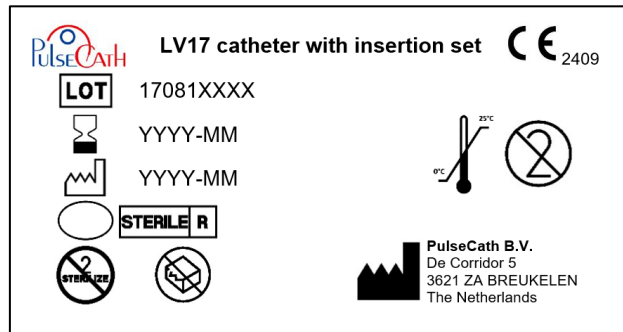
Attachment 1-PulseCath L iVAC 2L 17Fr-4

PulseCath L iVAC 2L 17Fr-4

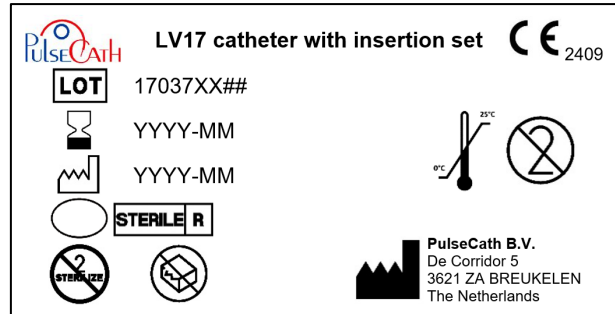
		
UDI  (01)08717953037275(17)221100(10)3825020		
		
		
		
	PulseCath B.V. De Corridor 5 3621 ZA, BREUKELEN The Netherlands	Phone: +31 (0) 346 23 0423 E-mail: info@pulsecath.com http://www.pulsecath.com

	PulseCath iVAC 2L[®] (17Fr)		
REF LV17  YYYY-MM LOT 3X#####	Contents: 1 x LV17 catheter with insertion set 1 x Membrane Pump 1 x Catheter Protector 1 x Extra PTFE Catheter Inner Tube		

Attachment 2-PulseCath L 17081CE-0

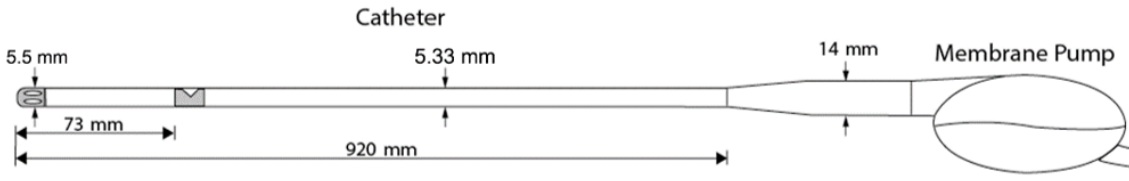
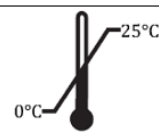


Attachment 3-PulseCath L 17037CE-4



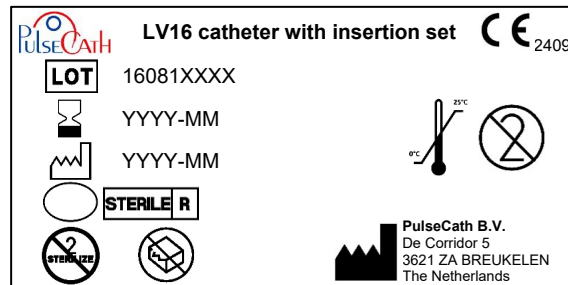
Attachment 4-PulseCath L iVAC 2L 16Fr-0

PulseCath L iVAC 2L 16Fr-0

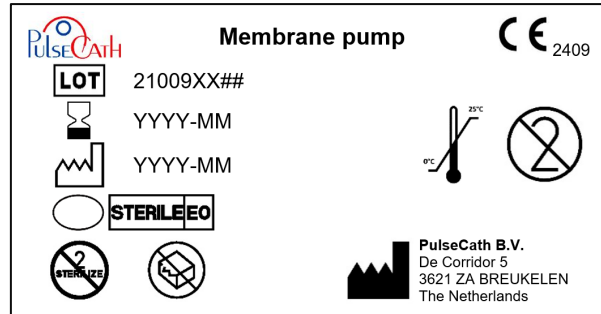
		
UDI  (01)08717953037275(17)221100(10)3825020		
		
		
		
	PulseCath B.V. De Corridor 5 3621 ZA, BREUKELEN The Netherlands	Phone: +31 (0) 346 23 0423 E-mail: info@pulsecath.com http://www.pulsecath.com

	PulseCath iVAC 2L[®] (16Fr)		
REF LV16  YYYY-MM LOT 3X#####	Contents: 1 x LV16 catheter with insertion set 1 x Membrane Pump 1 x Catheter Protector 1 x Extra PTFE Catheter Inner Tube		

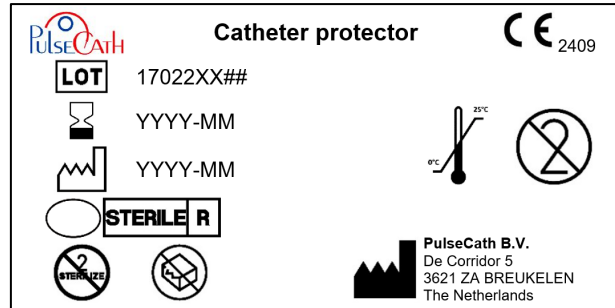
Attachment 5-PulseCath L 16081CE-0



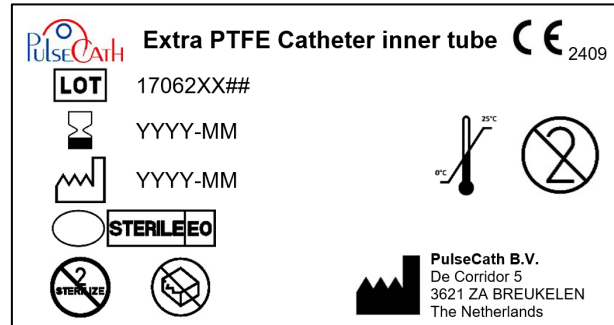
Attachment 6-PulseCath L 21009CE-6



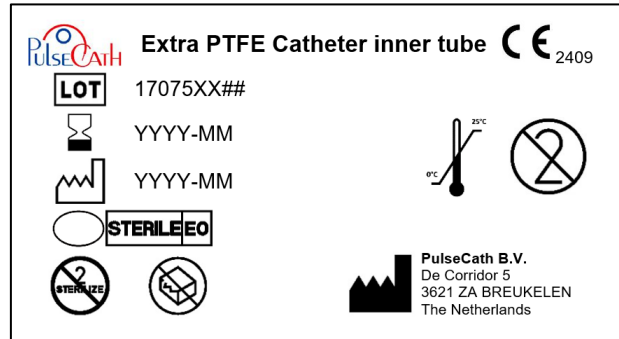
Attachment 7-PulseCath L 17022CE-4



Attachment 8-PulseCath L 17062CE-5



Attachment 9-PulseCath L 17075CE-0



TD A2 2.1.0-Device and Package Labels_REV7

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