

Design Dossier

Type : DD
 Title : **Labelling**
 Document No : DD LV17 7
 Revision : 7
 Date of Issue : 20 July 2022

Approved TT :  
 Oren Malkin (Jul 20, 2022 20:53 GMT+2)

Date of approval : 20-Jul-2022 20-Jul-2022

Every item packed in the iVAC 2L has its own label. On the label, the information is provided sufficient to trace the items back to the materials used as well as the specific sterilisation lot, if applicable.

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

Part number:	Part description:	Valid Label filename
LV17	PulseCath iVAC2L (17 Fr.)	PulseCath L iVAC 2L 17Fr-1
17037	LV17 catheter with insertion set	PulseCath L 17037CE-2
21009	Membrane Pump	PulseCath L 21009CE-4
17022	Catheter Protector	PulseCath L 17022CE-2
17062	Extra PTFE Catheter inner tube	PulseCath L 17062CE-3

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

The Membrane Pump (21009) is the same Membrane Pump as used in the iVAC 3L / iVAC 3L ST. For an example of the label of the Membrane Pump see DD LV21 7.

Note that the LOT number of the LV17 is composed of a merge:

1. Number 3,
2. one letter and
3. five numbers.

Note that the LOT number of components is composed of a merge:

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

Regional labels

For some non-EC countries that require some additional country specific information, an additional regional label is placed on the iVAC 2L.

The next table refers to these countries and their corresponding label filename. An example of these labels can be found in attachment 6.

Country	Valid Label filename
Indonesia	PulseCath L LV17 regional id-0
Malaysia	PulseCath L LV17 regional ms-0
Thailand	PulseCath L LV17 regional th-0

Attachments

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

Attachment 2-PulseCath L 17037CE-2

Attachment 3-PulseCath L 21009CE-4

Attachment 4-PulseCath L 17022CE-2

Attachment 5-PulseCath L 17062CE-3

Attachment 6-Regional labels

Changes

Rev 7: Lot number example text provided in such a way that it is unambiguous, and cannot be mistaken for the part number. Changed the description of label part 17062 from “PTFE Insertion Tubing” to “Extra PTFE Catheter inner tube” to align with the IFU. Revised PulseCath L iVAC 2L 17Fr by adding “Extra” before Catheter Inner Tube and revising the figure to provide dimensions of the catheter more clearly. Added regional labels for products to be shipped to Indonesia, Malaysia and Thailand.

Rev 6: Combined the labels “PulseCath L LV17CE” and “PulseCath LV17-1SP without Solopath” into one label “PulseCath L iVAC 2L 17Fr”. Updated the bar code format to the GS-128 standard. Added symbol for MD. Removed Extension Tube from iVAC 2L contents. Refer to CCF0051 for more details.

Rev 5: Added temperature symbol to each label and added “single pack LV17 without Solopath” label.

Rev 4: Added part number, description and filename of label single pack LV17. Rev 3: PTFE tubing added (CCF0024), label revision LV17 updated.

Rev 2: change of Notified Body number, new address and addition of CE logo and other icons.









Rev 1: Label PulseCath L LV17 changed to rev1 due to catheter valve position changed from 30 cm from tip to 6 cm from tip.

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

<p>(01)08717953037275(17)230400(10)3C01000</p>		
<div style="border: 1px solid black; padding: 2px; display: inline-block;">STERILE</div>		
	PulseCath B.V. Nieuwe Stationsstraat 20 6811 KS, ARNHEM The Netherlands	Phone: +31 (0) 26 352 7490 Fax: +31 (0) 26 845 8422 E-mail: info@pulsecath.com http://www.pulsecath.com

	PulseCath iVAC 2L[®] (17Fr)	<div style="border: 1px solid black; padding: 2px; display: inline-block;">MD</div>	CE ₂₄₀₉
<div style="border: 1px solid black; padding: 2px; display: inline-block;">REF</div> LV17 YYY-YY-MM <div style="border: 1px solid black; padding: 2px; display: inline-block;">LOT</div> 3X#####	Contents: <ul style="list-style-type: none"> ▪ 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 17037CE-2

		 2409
LV17 catheter with insertion set		
 LOT	17037XX##	 
	YYYY-MM	
 STERILE R		
	Attention, see instructions for use	
		Manufactured by: PulseCath b.v. Nieuwe Stationsstraat 20 14 th floor 6811 KS ARNHEM The Netherlands







Attachment 3-PulseCath L 21009CE-4

	Membrane pump	
LOT	21009XX##	
	2999-12	
STERILE		Manufactured by: PulseCath b.v. Nieuwe Stationsstraat 20 14 th floor 6811 KS ARNHEM The Netherlands
EO		
	Attention, see instructions for use	

Attachment 4-PulseCath L 17022CE-2

		 2409
	Catheter protector 17Fr	
 LOT	17022XX##	
	YYYY-MM	
 STERILE R		Manufactured by: PulseCath b.v. Nieuwe Stationsstraat 20 14 th floor 6811 KS ARNHEM The Netherlands
	Attention, see instructions for use	

Attachment 5-PulseCath L 17062CE-3

		 CE 2409
Extra PTFE Catheter inner tube		
LOT	17062XX##	 
	YYYY-MM	
STERILE EO		Manufactured by: PulseCath b.v. Nieuwe Stationsstraat 20 14 th floor 6811 KS ARNHEM The Netherlands
	Attention, see instructions for use	

Attachment 6-Regional labels

PulseCath L LV17 regional id-0

Additional labeling for products shipped to Indonesia:

Imported by:
PT. Qualtek Konsultan Jakarta
Tangerang-Indonesia

KEMENKES RI AKL 30503220036

PulseCath L LV17 regional ms-0

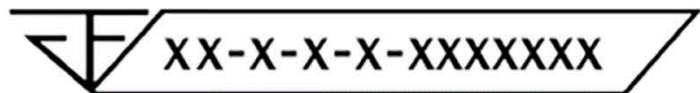
Additional labeling for products shipped to Malaysia:

Malaysia Authorised Representative:
Name: Qualtek Consulting Sdn. Bhd.
(201401028226)
Address: N-10-01, First Subang, Jalan SS15/4G,
47500 Subang Jaya, Selangor, Malaysia.
Contact Info: qualtek@qualtechs.com
MDA Registration No:

PulseCath L LV17 regional th-0

Additional labeling for products shipped to Thailand:

Imported by:
Qualtech Consulting (Thailand) Co., Ltd.
17th Floor, Promphan Building 3, Unit
1702, No.3, Ladprao Soi 3, Ladprao
Road, Chom Phon, Chatuchack, Bangkok











DD LV17 7-7_Labelling

Final Audit Report

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