Design Dossier

Type	:	DD
Title	:	**Declation of Conformity**
Document No	:	DD LV17 6.1
Revision	:	6
Date of Issue	:	18 April 2023

Approved TT : Oren Malchi (Apr 19, 2023 09:19 GMT+8)

Date of approval : 18APR2023 Apr 19, 2023

Changes:

Rev 6: reference to Annex V of MDD removed (was applicable for HV21 product, a class 1s medical device, not for iVAC 2L)

Rev 5: update to mention the PTFE insertion tubing

Rev 4: update of the Declaration after recertification of the product; change of certification numbers.

Rev 3: terminology on page 2 “Authorized Representative” changed in “signatory” in order to prevent confusion.

Rev 2: PTFE insertion tubing added to product list.

Rev 1: first review and approval of the product; in connection with the re-location of the company to Arnhem the new address specified.

DECLARATION OF CONFORMITY

iVAC 2L

We hereby declare that the distributed CE-marked product, specified in the annexed product list, conform to the type(s) covered by the EC Design Examination Certificate, reference number 144877-19-04-08, issued for the first time on 8 April 2019 and delivered by CE Certiso Kft. Hungary, Notified Body Identification Number 2409, in accordance with Annex II excluding (4) of the European Directive on Medical Devices (Council Directive EC DIR 93/42/EEC of June 14th concerning Medical Devices)

In addition, we ensure and declare that the distributed CE-marked products, as mentioned, falling in Risk Class III, meet the provisions of the European Medical Device Directive, which apply to them.

This declaration is based on the application of a Quality Management System approved for the design, manufacture and final inspection of the products concerned, in accordance with the procedure set out in Annex II, as described in the EC Certificate for Full Quality Assurance System, reference number 144876-19-04-08, issued for the first time on 8 April 2019 and delivered by CE Certiso Kft.

This Declaration of Conformity covers the iVAC 2L (LV17) as specified in the product list attached to this declaration and is valid for all products concerned bearing the CE-mark and manufactured at the following address:

PulseCath B.V.

Nieuwe Stationsstraat 20

6811 KS ARNHEM

The Netherlands

Signatory: Oren Malchin (Apr 19, 2023 09:19 GMT+8)

Oren Malchin

Acting CEO

PulseCath B.V.

Arnhem, date: Apr 19, 2023

Annex: Product List

PRODUCT LIST

This product list belongs to the Declaration of Conformity and specifies the CE-marked products concerned that PulseCath B.V. intends to distribute in conformity with the provisions of the European Directive on Medical Devices (Council Directive EC DIR 93/42/EEC of June 14th concerning Medical Devices). The following list identifies the products by name, article number and the first lot number.

Product name	Article number	First Lot number
PulseCath iVAC 2L (17Fr.) (Class III)	LV17	03B13001

- LV17 catheter with insertion set
- PTFE insertion tubing
- Membrane Pump
- Catheter Protector

The PulseCath iVAC 2L is a catheter based left ventricular circulatory support device.