Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**PulseCath B.V.**
Manufacturer address and contact details	De Corridor 5, 3621 ZA, Breukelen The Netherlands
Single Registration Number (SRN) (if available)	NL-MF-000006626

Notified body name (if applicable)	CE Certiso Kft. □ See attached schedule
Notified body number (if applicable)	2409 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	Certificate #1: 144876-19-04-08; Certificate #2: 144877-19-04-08; □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Certificate #1 & #2: 07 April 2024 □ See attached schedule
End date of extended validity/transition period	31 December 2027 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device** in the attached schedule and we as the manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed in the attached schedule

- Directive Certificate covering the listed device was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

The certificate /expires after 20 March 2023 and a formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body no later than 26 May 2024 for the device listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)***:*

A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device as listed in the attached schedule**

- The device) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

As additional objective evidence for the above declaration, a statement issued by the Notified Body CE Certiso is available.

Change of address

The address of PulseCath registered place of business has been changed after issuance of the Directive Certificates.

This does not affect the validity of the Directive Certificates.

Pursuant to Article 120 (1) of Regulations (EU) 2017 /745, since 26th May 2021, no certificate under the Medical Device Directive 93/42/EEC is allowed to be issued anymore by the notified body.

A statement issued by the Notified Body is available confirming the validity of the Directive Certificates with the address change.

Signed for and on behalf of the manufacturer:

Full Company Name	**PulseCath B.V.**	Print Name	**Oren Malchin**
Location & Date	**Breukelen, 12 June 2024**	Title	**CEO**
Signature	Om (Jun 12, 2024 17:21 GMT+2)	Contact Details	**Oren@PulseCath.com**

Schedule of Devices

The above Manufacturer's Declaration is valid for the following device:

Identification of the device(s)[2] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Device Name : iVAC 2L Catalogue number: LV17	144876-19-04-08 and 144877-19-04-08	07 April 2024	CE Certiso Kft. NB2409	CE Certiso Kft. NB2409	31 December 2027	Not applicable

[2] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters I and III

145213-24-03-01

CE Certiso Kft. (NB 2409) certifies, that the following manufacturer's quality management system concerning the devices and device categories meets the relevant requirements of the regulation.

Manufacturer:

PulseCath B.V.

Registered place of business: **De Corridor 5, 3621 ZA, Breukelen, The Netherlands**

Single registration number: **NL-MF-000006626**

The certificate covers the devices listed on the following pages.

Sampling was not applied during the technical documentation assessment. The harmonised standards and the common specification were considered during the assessment referred to below.
This certificate is valid only in case of surveillance audits successfully conducted at least once every 12 months.
In the case of Class III devices, this certificate independently does not authorize the manufacturer to use the CE mark on the devices.

This certificate is valid with the following conditions and/or provisions: ---

ID number of the relevant reports: **65-CE-220118, 65-G1-220119**

Issue: 2
Issued: 27 May 2024
First issued: 01 March 2024
Start date of certified status: 01 March 2024

Date of expiry:
28 February 2029

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Dr. Papp Valter
General Manager

CE Certiso Ltd. NB2409 Notified Body

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 on Medical devices
Annex IX Chapters I and III

145213-24-03-01

Devices covered by this certificate:

Identification of the device	EMDN code	Model/ Type	Basic UDI-DI	Intended use	Risk class
Catheter-based ventricular circulatory support devices and accessories	C019001 Aortic counterpulsation catheters	iVAC 2L/ LV17	87179530372 iVACEG	The iVAC 2L is intended for use in patients with impaired left ventricular function, which requires left ventricular mechanical circulatory support for up to 24 hours. It is intended to be used together with an IABP driver. Indications: A cardiologist and or cardiac surgeon will determine if support with the iVAC 2L is the appropriate option. This is based on one or more of the following clinical and/or anatomical criteria. Clinical criteria: • Acute coronary syndromes (ACS) • Chronic kidney disease • Diabetes mellitus • Hemodynamic instability • Left ventricular ejection fraction (LVEF) of <40% • Previous cardiac surgery Anatomical criteria: • Diffuse CAD • Last patent conduit • Multivessel disease • Severe coronary total occlusion • Severely calcified lesions needing rotational atherectomy • Unprotected left main coronary disease involving bifurcation	III

Certificate revision history:

Issue	Date of issue	Description of changes
1	01.03.2024	Issued.
2	27.05.2024	Change of registered place of business.

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
H-2092 Budakeszi, Erdő u. 101.
Adószám: 23147049-2-13

Issue: 2
Issued: 27 May 2024

CE Certiso Ltd. NB2409 Notified Body

Dr. Papp Valter
General Manager

CE Certiso Kft.
H-2092 Budakeszi, Erdő utca 101.
Contact.: +36 23 880 830 / info@cecertiso.hu / www.cecertiso.hu
NB identification: 2409