PulseCath B.V.
De Corridor 5
3621 ZA BREUKELEN
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EU Declaration of Conformity

iVAC 2L

We:

Manufacturer Name:	PulseCath B.V.
SRN:	NL-MF-000006626
Address:	De Corridor 5
Postal code:	3621 ZA
City:	BREUKELEN
Country:	The Netherlands

declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and applies to the following medical device:

Product name:	iVAC 2L
Catalogue number:	LV17
Basic UDI-DI:	87179530372iVACEG
Risk class and Rule:	Class III, Rule 7
Intended Purpose:	The iVAC 2L is intended for use in patients with impaired left ventricular function who require left ventricular mechanical circulatory support for up to 24 hours. The iVAC 2L Tip should be positioned in the left ventricular cavity through the femoral artery.

The device covered by the present declaration is in conformity with the Regulation (EU) 2017/745 on Medical Devices. No common specifications were applied.

A conformity assessment procedure has been followed based on quality management system and assessment of the technical documentation described in Chapters I and II of Annex IX of the MDR.

The conformity assessment procedure involved the notified body:

Name:	CE Certiso
Notified Body number:	2409
Identification of certificates issued:	145213-24-03-01 and 145214-24-03-01

Place of issue: Breukelen Date of issue: June, 11 2024 Signature: _____

Oren Malchin, CEO, PulseCath B.V.