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 compliance of the devices and we, as the legal manufacturer of these devices, with the conditions for the continued placing on the market and putting into service:

Manufacturer's Name:	**Bioptimal International Pte. Ltd.**
	36 Jalan Tukang, #02-02 SINGAPORE 619266
Telephone / Fax:	+65 6213 5777 / +65 6213 5737
Email:	ra-bpi@bioptimalg.com
Website:	www.bioptimalg.com
Single Registration Number:	SG-MF-000010306
EU Representative:	**Shanghai International Holding Corp. GmbH (Europe)**
	Eiffestrasse 80, 20537 Hamburg, GERMANY
Telephone / Fax:	+49 40 2513175 / +49 40 255726
Email:	shholding@hotmail.com
Single Registration Number:	DE-AR-000000001
Notified Body:	**DEKRA Certification B.V**
	Meander 1051, 6825 MJ Arnhem, The NETHERLANDS
Notified Body Number:	**0344**
EC Certificate No.:	2181711CE01
CE Marking under DEKRA:	First issued on 15 July 2015; reissued and revised on 30 March 2020 with validity until 26 May 2024
Extended validity period:	**31 December 2027 – Class III**
	31 December 2028 – Class IIa

We, as the legal manufacturer of the devices in **Annex 1** under declaration, do hereby declare under our sole responsibility that we, as the legal 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 Annex 1.**
  - Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - Formal application to a 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 devices listed in Annex 1 and a signed written agreement is already in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

➢ **Devices as listed in Annex 1**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The devices 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.

[redacted]

BIOPTIMAL INTERNATIONAL PTE. LTD.

Francis Joey Eduave
Person Responsible for Regulatory Compliance (PRRC)
On behalf of Bioptimal International Pte. Ltd.
36 Jalan Tukang, #02-02 SINGAPORE 619266
ra-bpi@bioptimalg.com

Annex 1

Schedule of Devices

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

Device Identification	Device Class	Directive Certificate(s) No.	Original Validity Date	Extended Validity Date
Central Venous Catheter and Catheterization Kit	Class III	2181711CE01 2181711DE01	26 May 2024	31 Dec 2027
Thermodilution Catheter and Kits (Biotray)	Class III	2181711CE01 2181711DE02	26 May 2024	31 Dec 2027
Pulmonary Artery Monitoring Catheter and Kits (Biotray)	Class III	2181711CE01 2181711DE02	26 May 2024	31 Dec 2027
Bipolar Pacing Catheter	Class III	2181711CE01 2181711DE03	26 May 2024	31 Dec 2027
Vascular Introducer Kit	Class IIa	2181711CE01	26 May 2024	31 Dec 2028
Pressure Monitoring Systems and Kits – ACCUTRANS/BIOTRANS/CATRANS	Class IIa	2181711CE01	26 May 2024	31 Dec 2028
Embolectomy Catheter	Class IIa	2181711CE01	26 May 2024	31 Dec 2028