Manufacturer Declaration
Extension of the transition period for legacy devices

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices,

We,

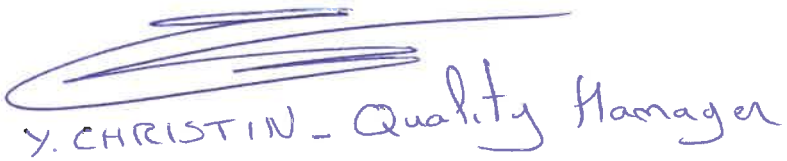
Manufacturer name Commercial name	**ELECTRONIC CONCEPT LIGNON INNOVATION** **VIVALTIS**
Manufacturer address and contact details	**200, rue de Thor - Parc Eureka** **34000 MONTPELLIER** **FRANCE**
Single Registration Number (SRN)	**FR-MF-000006594**

declare under our sole responsibility the amendments to Article 120 of the MDR, as set out in Art. 1 of Regulation (EU) 2023/607, apply to the devices listed in the attached table and that the following conditions laid down in Reg (EU) 2023/607 are met :

- The devices continue to comply with the MDD (Directive 93/42/EEC).
- 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.
- The devices comply with the MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices;
- A QMS in accordance with Article 10(9) MDR is in place.
- 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 for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

ELECTRONIC CONCEPT LIGNON INNOVATION
Montpellier, July 27, 2023

Signature, Print Name, Title



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

Directive Certificate number to which this confirmation is made	15311	**Notified Body name and number that issued the Directive Certificate**		GMED 0459
Notified Body name and number where the MDR application was lodged/contract signed		GMED 0459		
Identification of the device(s)	**Basic UDI-DI**	**Class of the device(s)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**End date of extended validity / transition period**
PHENIX Liberty	376035357LIBERTYLT	IIb	26 May 2024	31 December 2028
PHENIX USB Néo	376035357USBNEOKX	IIb	26 May 2024	31 December 2028
PHENIX NANO Portable Uro	376035357PORTNANOEV	IIa	26 May 2024	31 December 2028
PHENIX NANO Portable Physio Uro	376035357PORTNANO1YV	IIa	26 May 2024	31 December 2028
PHENIX NANO Portable Physiostim	376035357PORTNANO2YX	IIa	26 May 2024	31 December 2028
PHENIX USB Micro	376035357USBMICROAN	IIb	26 May 2024	31 December 2028
PHENIX USB Micro Full	376035357USBMICROAN	IIb	26 May 2024	31 December 2028
POD Stim/bio	376035357PODSTIMBIONH	IIb	26 May 2024	31 December 2028
POD Interférentiel	376035357PODINTER7Q	IIb	26 May 2024	31 December 2028
POD MultiPatients	376035357PODMPEX	IIb	26 May 2024	31 December 2028
POD Universel	376035357PODUNIVERSELRL	IIa	26 May 2024	31 December 2028
Manomètre numérique 1 V	376035357MANONUMP5	IIa	26 May 2024	31 December 2028
Manomètre numérique 2 V	376035357MANONUMP5	IIa	26 May 2024	31 December 2028
Manomètre numérique 3 V	376035357MANONUMP5	IIa	26 May 2024	31 December 2028
Sonde Tulipe	376035357SONDETULIPEMT	IIa	26 May 2024	31 December 2028