

## 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
- 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	Christeyns France
Manufacturer address and contact details	31, Rue de la Maladrie 44120 Vertou – France
Single Registration Number (SRN) (if available)	FR-MF-000034556

Authorised Representative name (if applicable)	Not applicable
Authorised Representative address and contact details	Not applicable
Single Registration Number (SRN) (if available)	Not applicable

Notified body name (if applicable)	GMED <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	0459 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	Additional document N° 37606 rev. 2 Certificate N° 31653 rev. 9 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26 <sup>th</sup> , 2024 <input type="checkbox"/> See attached schedule
End date of extended validity/transition period	December 31 <sup>st</sup> , 2028 <input type="checkbox"/> See attached schedule

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(s)** in the attached schedule and we as their 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 above or in the attached schedule

- Directive Certificate covering the listed device(s) was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.
  - ☐ 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 before 26 May 2024 for the device listed in the attached schedule and a signed written agreement will be 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 is in place.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) 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.

**Signed for and on behalf of the manufacturer:**

Christeyns France

Vertou, July 15<sup>th</sup> 2024

Marie-Bénédicte Sionneau, Scientific and Regulatory Director & PRRC

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## Schedule of Devices

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

<b>Identification of the device(s)<sup>1</sup></b> (e.g., device name, family/group name, device model or catalogue number)	<b>Directive Certificate number(s) to which this confirmation is made</b> (if applicable)	<b>Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity</b> (if applicable)	<b>Notified Body name and number that issued the Directive Certificate</b> (if applicable)	<b>Notified Body name and number where the MDR application was lodged/contract signed</b> (if applicable)	<b>End date of extended validity / transition period</b>	<b>Substitute Device(s)</b> (if applicable)
PHAGO'SCOPE APA	Additional document N° 37606 rev. 2 Certificate N° 31653 rev. 9	May 26 <sup>th</sup> , 2024	GMED N° 0459	TUV SUD 0123	December 31 <sup>st</sup> , 2028	Not applicable

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<sup>1</sup> 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