EU Declaration of Conformity
(Regulation (EU) 2017/745 of the European Parliament and the Council)

Manufacturer: INTRASENSE

Single Registration Number: SRN FR-MF- 000001551

Address: 1231, avenue du Mondial 98, 34000 Montpellier, France

Tradename of Device: Myrian® software suite V2.12 (Product code, catalogue number)

Basic UDI-DI: 37007197MyrianGW

Classification: **Class IIa (According to Rule "11" of Annex VIII of Regulation (EU) 2017/745)**

**I, the undersigned, hereby declare and ensure that the device covered by the present declaration is in conformity with the Regulation (EU) 2017/745. This declaration is issued under the sole responsibility of INTRASENSE. Any modification of the medical device not authorized by INTRASENSE will invalidate this declaration.**

The devices specified above meet general safety and performance requirements of Annex I of the Regulation (EU) 2017/745.

All evidence is documented in the technical documentation of the device according to Annex II and III of the Regulation (EU) 2017/745.

The conformity of the full quality assurance system according to Annex IX (Chapters I and III, point 4 of Chapter II) of Regulation (EU) 2017/745 is certified by:

**GMED, 1 Rue Gaston Boissier – 75015 Paris**
Notified body Identification number: **0459**
Certificate # : **39581 rev.2**

Signed for and on behalf of manufacturer:

Place and date: **Montpellier, France Friday, 26 April 2024**

Name:
Quality and regulatory affairs Manager
Signature: 26/04/2024 _____

DocuSigned by:
Nicolas Di Francesco
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