EU Declaration of Conformity
(Directive (EU) 93/42/EEC 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 2.9.13

Basic UDI-DI: n/a

Classification: Class IIa (According to Rule "10" of Annex IX of Directive 93/42/EEC)

I, the undersigned, hereby declare and ensure that the device covered by the present declaration is in conformity with the Directive 93/42/EEC. 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 essential requirements of Annex I of the Directive (EU) 93/42/EEC.

All evidence is documented in the technical documentation of the device according to Annex I of the Directive (EU) 93/42/EEC.

The conformity of the full quality assurance system according to Annex II excluding section 4 of Directive (EU) 93/42/EEC is certified by:

Name and address of the notified body: **GMED, 1 rue Gaston Boissier, 75015 Paris**
Notified body Identification number: **0459**
Certificate: **12895 rev. 12**

The covered device benefits from the extension of 93/42/EEC certification (more precisely from the transitional provisions of the EU Regulation 2017/745 following amendment 2023/607).

Reference of confirmation letter: **39653 rev. 0**

The transition timelines that apply to the devices covered by this letter is: 31 December 2028 for Class IIa device.

Signed for and on behalf of manufacturer:

Place and date: **Montpellier, France Monday, 29 April 2024**

Name: Nicolas Di Francesco
Quality and regulatory affairs Manager
Signature: DocuSigned by: Nicolas Di Francesco 4/29/2024
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