AMINOGram
Bioimpédancemétrie & Innovation

EU DECLARATION OF CONFORMITY

According to Annex XI-Part A-Section 10 included in Regulation (EU)2017/745 on medical devices

We, the manufacturer,
SRN: FR_MF_000000671

AMINOGRAM
ZI Athélia II - 96 Voie Atlas- lot 7
13600 LA CIOTAT - FRANCE

guarantee and declare, under our sole responsibility, that the device:
IUD-ID Base: 3760073650003WU

BIODY XPERT^{ZM} 3
Class IIa according to Rule 10 of Annex VIII of Regulation (EU)2017/745.

Meets the requirements of Regulation (EU)2017/745 applicable to it, the French Public Health Code, as well as the following directives:

2011/65/EU – Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
2012/19/EU – Directive on waste electrical and electronic equipment (WEEE)
2014/53/EU – Directive on the making available on the market of radio equipment (RED)
1907/2006 – Regulation concerning the registration, evaluation, authorization, and restriction of chemicals (REACH)

This declaration is based on the following elements:

- Technical File (DT_BX3) rev3 demonstrating compliance with the general requirements of Regulation (EU)2017/745
- CE Certificate: 39919 rev. 0 issued by the notified body No. 0459

Validity start: 01/07/2024
Validity end: 30/06/2029

- Certificate 39728 rev. 0 of quality system approval according to ISO 13485:2016 issued by the notified body No. 0459

Validity start: 29/04/2024
Validity end: 28/04/2027

This declaration of conformity is valid from the date of its signature and for the validity period of the certificate, i.e., until 30/06/2029.

Done in La Ciotat on 23/05/2025

Mélody LETOURNEUR
President