SUBJECT: **CE DECLARATION OF CONFORMITY** of the device branded **AMNIORAM – AMNIOCENT ref. 770212, 770228, 770222, 770224, 770201, 770226, 770227, 770223, 770202, 770229, 770232, 772007, 772004, 772006, 772001,** manufactured by RI.MOS. Srl according to Annex II of 93/42/CEE Directive, subsequently modified by 2007/47/CEE Directive and acknowledged in Italy with Law "D.Lgs 25th January 2010 n.37".

The undersigned company RI.MOS. Srl, located in Mirandola (MO), Via Manuzio, 15, manufacturer of above mentioned devices

DECLARES

Under its own responsibility that the devices in reference meets all applicable regulations within 93/42/CEE Directive about medical devices subsequently modified by 2007/47/CEE Directive and acknowledged in Italy with Law "D.Lgs 25th January 2010 n.37".

Therefore, the undersigned herewith guarantees and declares under its own responsibility the following:

- The device meets all essential requirements as requested by Annex I of 93/42/CEE Directive.
- The device is to be considered as belonging to **Class II a.**
- The device IS NOT A MEASURING INSTRUMENT.
- Sterilization is performed by Oxide of Ethylene validated method, in conformity with EN 11135 and EN 556 Standards;
- All devices are manufactured under a certified Quality Managing System according to UNI EN ISO 13485 Standard;
- IMQ spa, Notifying Body no. 0051, **Via Quintiliano, 43 – 20133 Milano Italy**, approved Quality System as per Attachment II with the exception of point 4 of the aforesaid Directive (certificate no. 2050/MDD expiring the 26/5/2024)
- All products are manufactured according to technical documentation as per attachment II with the exception of point 4 (production quality guarantee)
- The manufacturer commits himself to store and keep all supporting documents at the disposal of Competent Authorities for a period of 10 years from latest manufacturing date of the product

Mirandola, 27th February 2024

Signature
QA/RA Manager

Claudia Gemelli
Regulatory Affairs
Ri.Mos. srl