AK MEDICAL S.R.L.
Via del Chioso N.10 - 24030 MOZZO (BG)
TEL. 035 613712 CELL.334 1807240
FAX 0544 1761249
Partita Iva-Codice Fiscale 02484810391
Site: http://www.akmedical.it
Mail info@akmedical.it commerciale@akmedical.it

DECLARATION OF CONFORMITY

The Company AK MEDICAL S.R.L. (SRN code no. IT-MF000011246) with headquarters in Via del Chioso no. 10 Mozzo (BG)

DECLARE

under its sole responsibility that the medical device referred to below:

DISPOSABLE AMNIOTIC MEMBRANE
REF. 0120 – CRT OF 600 PCS
CND n.U089004 GMDN 12990 REPERTORY NUMBER 1382704
UDI-DI BASIC 805210711PerfAmnio0120EX

belong to risk class I sterile, in accordance with rule 5 of Annex IX of Directive 93/42/EEC and subsequent amendments. (amended by Dir.2007/47/EC) implemented in Italy with Legislative Decree 24 February 1997, n.46 and subsequent amendments. (amended with Legislative Decree no. 37/10) and the applicable requirements of EU regulation 2017/745:

- **comply with** the essential requirements and provisions of Directive 93/42/EEC and subsequent amendments. as per technical file no. FT.001.AK archived at the operational headquarters of AK MEDICAL S.R.L.
- **they are manufactured** in accordance with the Quality System that meets the requirements set out in Annex V of the aforementioned legislative decree as per certificate no. 0425-MED-003496-00 issued on 01/30/2019 expired on 01/29/2024 extended to 12/31/2028 as required by EU regulation 2023/607 and by "Confirmation letter" issued by ICIM S.P.A.- Organism Notified no. 0425 – Piazza Don Enrico Mapelli n.75 - 20099 Sesto San Giovanni (MI) on 06/06/2023.
- **they are sterile –** Sterilized with ethylene oxide.

Mozzo, 06 february 2024

Il Legale Rappresentante
AK MEDICAL S.r.l.
(Annachiara Giacometti)