



AK MEDICAL S.R.L.
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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:

STERILE DISPOSABLE PAP TEST SET - BOX OF 100 PCS

REF. 0196 composed of: n.1 brush, n.1 mini container, n. 2 slides, n. 1 Ayre spatula and n.2 latex gloves

REF.0195 composed of: n.1 Speculum with medium central pin, n.2 gloves for exploration, n.1 mini container with two slides, n.1 Ayre spatula, n.1 brush

CND U0899 REPERTORY 1382628 GMDN 37468

UDI-DI-BASIC 805210711KitPaptest01xxF6

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)
Annachiara Giacometti