AK MEDICAL S.R.L.
Via del Chioso N.10 - 24030 MOZZO (BG)
TEL. 035 613712 CELL.334 1807240
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 n. IT-MF000011246) with headquarters in Via del Chioso n. 10 Mozzo (BG)

DECLARE

under his own total responsibility that the medical device named:

DISPOSABLE ANOSCOPE
REF.0601
CND G02060301 REPERTORIO 1382877 GMDN 44914
UDI-DI BASIC 805210711Anoscopio06016U

It belongs 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 by Legislative Decree no. 37/10) and the applicable requirements of EU regulation 2017/745:

- **complies** with the essential requirements and provisions of Directive 93/42/EEC and subsequent amendments. and the applicable requirements of EU regulation 2017/745 as per technical file n. FT.001.AK filed at the operational headquarters of AK MEDICAL S.R.L.

- **are manufactured** in accordance with the Quality System that satisfies the requirements set out in Annex V of the above-mentioned 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.- Notified Body no. 0425 – Piazza Don Enrico Mapelli n.75 - 20099 Sesto San Giovanni (MI) on 06/06/2023.

- **Sterilized** with Ethylene Oxide

Mozzo, 06 luglio 2024

AK MEDICAL S.r.l.