



AK MEDICAL S.R.L.
Via del Chioso N.8/10 - 24030 MOZZO (BG) Italia
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)

DECLARES

under its own responsibility that the medical devices named

DISPOSABLE UMBILICAL CORD CLAMP
REF.0111/L
CND V0202 - REPERTORY 1382691 - GMDN 32192
UDI-DI Basic 805210711Pinombelico111U6

belongs to risk class I sterile, in accordance with rule 4 , of Annex IX to Directive 93/42/EEC and ss.mm.ii. (issued by Dir.2007/47/EC) transposed in Italy by Legislative Decree February 24, 1997 no. 46 and ss.mm.ii. (issued with D.L.gs. n. 37/10):

- **complies** with the essential requirements and the provisions of Directive 93/42/EEC and ss.mm.ii. as per technical file n. FT. 001.AK filed at the headquarters of AK MEDICAL S.R.L.
- **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 and expired on 01/29/2024, extended to 12/31/2028 in accordance with EU Regulation 2023/607 with "confirmation letter " issued by ICIM S.P.A.- Notified Body No. 0425- Piazza Don Enrico Mapelli No. 75 - 20099 Sesto San Giovanni (MI) on 06/06/2023.
- **is sterilized** with Ethylene oxide

Mozzo, April 30 2025

AK MEDICAL S.r.l.