ARIES S.r.l.
Biomedical Devices

# *DECLARATION OF CONFORMITY*

Declaration of CE Conformity of medical device indicated as: **CHEMODRIP – I.V. SOLUTIONS SET FOR INFUSION PUMP** manufactured by ARIES s.r.l., according to Annex V and Annex VII of MDD 93/42/EEC consolidated with the requirements of the Amending Directive 2007/47/EC.

The undersigned company ARIES s.r.l located in Mirandola 41037 (MO) – Via XXV Luglio, 43 - Vat N° 022847660366., manufacturer of **CHEMODRIP – I.V. SOLUTIONS SET FOR INFUSION PUMP, (IN014004),** guarantees and declares under its own responsibility the following:

- That the a.m. devices satisfy all essential requirements as requested by the Annex I and dispositions of MDD 93/42/EEC consolidated on medical devices;
- That the a.m. devices are of Class **IIa** (Rule 2 MDD 93/42/ECC consolidated);
- That the a.m. devices are LATEX FREE;
- That the a.m. devices are commercialised in **sterile** packaging;
- That ARIES will file and maintain disposal to the Notified Body the technical documentation, as specified in Annex VII, point 3, of MDD 93/42/CEE consolidated, as well as registrations and tests of production for a period of 10 years from the last date of production of the device.
- That the harmonized standards applicable to the medical device are listed in the Section 01 of the Technical File (FT 18);
- That the a.m. devices are manufactured and commercialised, as indicated in the technical file of the product, within the specifications of Quality System in compliance with ISO 9001 and ISO 13485 from TÜV SÜD Product Service GmbH, notified Body as requested by MDD 93/42/EEC consolidated number 0123, as pointed out in Annex V of a.m. directive (ref: Certificate CE: G2 031848 0017 Rev.01 valid from 2021/02/16 until 2024/05/26 – Start EC Mark date 2007.04.23)
- That ARIES guarantees to establish and to maintain a valid procedure in order to guarantee post-marketing surveillance as requested by MEDDEV 2.12/1.

The undersigned Company ARIES s.r.l., with this declaration, authorizes TÜV SÜD Product Service GmbH, Ridlestrasse 65, 80339 München, Germany, to carry out the necessary inspection to verify the respect of the obligation of which to the Annex V of MDD 93\42\CEE.

When a medical device batch is issued, Q.A. verifies that the validity of the CE certificate of OEM manufacturer is in force and fill Mod. 85, which is a declaration of conformity of device, for each batch of production.

This Certificate applies to all medical devices produced by 2024/05/26 and refers to the entire family of devices listed in this file.

A declaration of conformity for each batch is briefly mentioned in the issued certificate.

ARIES S.r.l.
CEO
*Maria Luisa Locatelli*

Mirandola: 2024/04/02