SVAS BIOSANA

# DECLARATION OF EC CONFORMITY

UNI CEI EN ISO/IEC 17050-1:2010

**IN ACCORDANCE WITH ANNEX VII**

**(Directive 93/42 / EEC and subsequent amendments implemented by Legislative Decree 46/97 and subsequent amendments)**

CE

| | |
|---|---|
| **Manufacturer** | **SVAS BIOSANA SPA** |
| Administrative Headquarters | Via Trentola, 7<br>80049 Somma Vesuviana (NA) - Italia |
| Medical device | Gelid – powder thickener for organic liquids |
| Model | ASPIDRAIN A |
| Class | I (secondo l'allegato IX della Dir. 93/42/CEE e s.m.i.) |
| CND code | A0680 |
| GMDN code | 58116 |
| Lot | XX 033 YYY |
| Catalogue Code | 1SVASC035050 |

The undersigned SVAS BIOSANA SPA **declares**, under its own responsability that the above mentioned devices dispositivi meets all the provisions of the directive 93/42/ EEC and following amendments.

Certified Quality System UNI EN ISO 9001:2015; UNI EN ISO 13485:2016

Moreover Svas Biosana SpA **declares** under what follows:

- The concerned devices meet the essential requirements as according to Annex I Directive 93/42/EEC as amended by Directive 2007/47/EC.
- The concerned devices are sold in a NOT STERILE packing;
- The concerned devices are NOT INSTRUMENTS OF MEASURE;
- The concerned devices are NOT DESTINED FOR CLINICAL INVESTIGATION;
- The manufacturer must undertake to maintain and make available to the Competent Authority the technical documentation specified in 'Annex VII of the Directive 93/42/EEC and following amendment for a period of at least five years from the date of manufacture of the last batch produced.

On behalf of SVAS BIOSANA SPA

Eng. Giovanna Angelillo
*Regulatory Affair*
*(Delegato alla Firma)*

*Somma V.na, 12.09.2022*

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