SVAS BIOSANA

DECLARATION OF EC CONFORMITY

UNI CEI EN ISO/IEC 17050-1

IN ACCORDANCE WITH ANNEX VII together with V of Directive 93/42 / EEC (amendment 2007/47 / EC) implemented with Legislative Decree 46/97 (amendment to Legislative Decree 37/2010)

CE

Manufacturer	**SVAS BIOSANA SPA**
Administrative Headquarters	Via Trentola, 7 80049 Somma Vesuviana (NA) - Italia
Medical device	**sterile lubricating gel with chlorhexidine**
Modello	*Farmagel C*
Classe	IIa(according to annex IX of Directive 93/42/EEC and following amendments)
Codice CND	V9007
GMDN Code	37717
Lot	XX 152 YYY
Catalogue Code	3SVASJ111012
Notify Body	KIWA CERMET - 0476 **N° MED26027 valido fino al 26.05.2024**

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 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 V 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
(Authorized Signatory)

Somma V.na, 09.09.2022

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