



SVAS BIOSANA

DECLARATION OF EC CONFORMITY

UNI CEI EN ISO/IEC 17050-1:2010

**IN ACCORDANCE WITH ANNEX II
Section 3, except Section 4**

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



Manufacturer	SVAS BIOSANA SPA
Administrative Headquarters	Via Trentola, 7 80049 Somma Vesuviana (NA) - Italia
Medical device	devices for the dressing of skin lesions
Model	ATTIVA GRAS
Class	I Ib (according to annex IX of Directive 93/42/EEC and following amendments)
CND Code	M040599
GMDN Code	148131
Lot	XX AGG YYY
Catalogue Code	3SVASM513059

Notify Body **ICIM S.P.A. - 0425**
Piazza Don Enrico Mapelli, 75 – 20099 – MI

The undersigned SVAS BIOSANA SPA **declares**, under its own responsibility 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 II (Section 3, with the exception of Section 4) 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)

 **SVAS BIOSANA SPA**
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