SVAS BIOSANA

DICHIARAZIONE DI CONFORMITÀ

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)

CE

Manufacturer	**SVAS BIOSANA SpA**
Administrative Headquarters	Via Trentola, 7 80049 Somma Vesuviana (NA) - Italia
Medical device	*YANKAUER CANNULA WITH BULB TIP AND SUCTION TUBE*
Model	ASPIJET SET
Class	IIa (according to annex IX of Directive 93/42/EEC and following amendments)
CND Code	A06010103
GMDN Code	47342
Lot	XX 032 YYY
Catalogue Code	1SVASC116120
Notify Body	ITALCERT - 0426
CE Certificate of Conformity	115-02-00– DM Valid until 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 II 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
(Authorized Signatory)
Regulatory Affairs

Somma V.na, 12.09.2022

SVAS BIOSANA S.p.A.
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