



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)**



Manufacturer

SVAS BIOSANA SpA

Administrative Headquarters

Via Trentola, 7
80049 Somma Vesuviana (NA) - Italy

Medical device

YANKAUER CANNULA WITH OPEN 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

1SVASC106120

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 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 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

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