

**CERTIFICATE N° 120-02-00-DM**

*(in compliance with Annex II of the Directive 93/42/EEC)*

**ITALCERT**

certifies that the

Full Quality Assurance System  
applied for the design, manufacture and final inspection  
of “Medical Devices” - MD -

by the manufacturer

**SVAS BIOSANA S.p.A.**

Via Perillo, 34 - 80047 S. GIUSEPPE VESUVIANO (NA) - ITALY

in the headquarters located in

Via Trentola, 7 - 80049 SOMMA VESUVIANA (NA) - ITALY  
Via Genio Militare, Loc. Pentelete - 80044 OTTAVIANO (NA) - ITALY

complies with the requirements stated in

**Directive 93/42/EEC - Annex II (excluding point 4)**

and authorizes the manufacturer to mark

**CE 0426**

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC  
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito

  
MANAGING DIRECTOR

First issue date  
2009-12-02

Date of renewal  
2019-12-18

Expire date  
2024-05-26

## Annex 1 to Certificate n° 120-02-00-DM

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### Medical devices and accessories for surgical use - class IIa / IIb -


- *Complete systems and kits for the operating field*

Macro-Family	Line	Family	Description
TraySet	2SVAST	YY	XXXX

- *Complete systems and kits for the operating field – Instruments Kit*

Macro-Family	Line	Family	Description
TraySet	2SVAST	M	XXXXXX
TraySet	2SVAST	M	XXXXXX
TraySet	2SVAST	M	XXXXXXXX
TraySet	2SVAST	M	XXXXXXXX
TraySet	2SVAST	M	XXXXXXXXXX
TraySet	2SVAST	M	XXXXXXXXXX

Milan, 2019-12-18

dr. ing. Roberto CUSOLITO  
  
Managing Director