

DECLARATION OF EC CONFORMITY

UNI CEI EN ISO/IEC 17050-1:2010

According to Annex II

(directive 93/42/EEC EEC as amended by the Directive 2007/47/EC)



Manufacturer

SVAS BIOSANA SPA

Head Office

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

Medical device

assembled for surgical procedures

Model

TRAY SET – KIT FOR DIAGNOSTIC INTERVENTIONS

Class

I Ib (as according to Annex IX Directive 93/42/CEE as amended by the Directive 2007/47/EC)

Code CND

T0202

Lot

AA 034 XXX

Code Catalogue

2SVAST020715

Notified Body

120-02-00- DM valid until 26 May 2024 - Italcert 0426

The undersigned SVAS BIOSANA SpA **declares**, under its own responsibility that the above mentioned device meets all the provisions of the directive 93/42/EEC

Certified Quality Systems

UNI EN ISO 9001:2015; UNI EN ISO 13485:2021

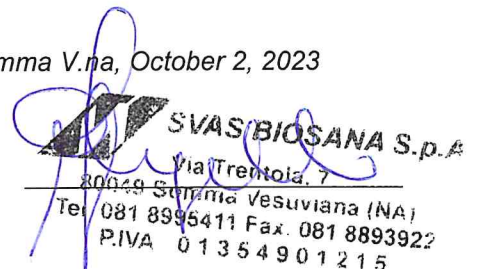
Moreover, Svas Biosana Spa guarantees and declares under its own responsibility what follows :

- The concerned devices meet the essential provisions as according to Annex I Directive 93/42/EEC as amended by the 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 SURVEYS.
- Svas Biosana SpA keeps and makes available to the Competent Authorities the technical documentation specified to annex II of Directive 93/42/EEC for a period of five years from the last production date of the medical devices.

SVAS BIOSANA SPA

Eng. Giovanna Angelillo
Regulatory Affairs
(delegated of the signature)

Somma V.na, October 2, 2023



SVAS BIOSANA S.p.A.
Via Trentola, 7
80049 Somma Vesuviana (NA)
Tel. 081 8995411 Fax. 081 8893922
P.IVA 01354901215

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UNI CEI EN ISO/IEC 17050-1:2010

According to Annex II

(directive 93/42/EEC EEC as amended by the Directive 2007/47/EC)



Manufacturer

SVAS BIOSANA SPA

Head Office

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

Medical device

assembled for surgical procedures

Model

TRAY SET – MAJOR ENDOVASCULAR KITS

Class

I Ib (as according to Annex IX Directive 93/42/CEE as amended by the Directive 2007/47/EC)

Code CND

T0202

Lot

AA 034 XXX

Code Catalogue

2SVAST020716

Notified Body

120-02-00- DM valid until 26 May 2024 - Italcert 0426

The undersigned SVAS BIOSANA SpA **declares**, under its own responsibility that the above mentioned device meets all the provisions of the directive 93/42/EEC

Certified Quality Systems

UNI EN ISO 9001:2015; UNI EN ISO 13485:2021

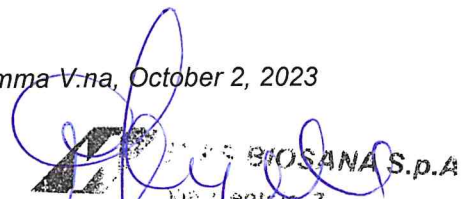
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Somma Vesuviana, October 2, 2023



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Manufacturer

SVAS BIOSANA SPA

Head Office

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

Medical device

assembled for surgical procedures

Model

TRAY SET – KIT FOR ANGIOGRAPHIC FIELD

Class

I Ib (as according to Annex IX Directive 93/42/CEE as amended by the Directive 2007/47/EC)

Code CND

T0202

Lot

AA 034 XXX

Code Catalogue

2SVAST020717

Notified Body

120-02-00- DM valid until 26 May 2024 - Italcert 0426

The undersigned SVAS BIOSANA SpA **declares**, under its own responsibility that the above mentioned device meets all the provisions of the directive 93/42/EEC

Certified Quality Systems

UNI EN ISO 9001:2015; UNI EN ISO 13485:2021

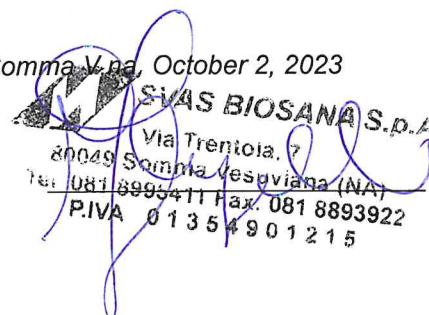
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Somma Vesuviana, October 2, 2023



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Manufacturer

SVAS BIOSANA SPA

Head Office

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

Medical device

assembled for surgical procedures

Model

TRAY SET – RADIAL APPROACH ANGIOGRAPHIC KIT

Class

IIb (as according to Annex IX Directive 93/42/CEE as amended by the Directive 2007/47/EC)

Code CND

T0202

Lot

AA 034 XXX

Code Catalogue

2SVAST020718

Notified Body

120-02-00- DM valid until 26 May 2024 - Italcert 0426

The undersigned SVAS BIOSANA SpA **declares**, under its own responsibility that the above mentioned device meets all the provisions of the directive 93/42/EEC

Certified Quality Systems

UNI EN ISO 9001:2015; UNI EN ISO 13485:2021

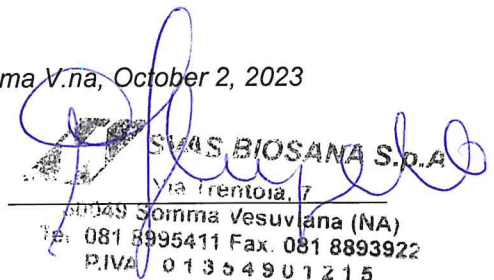
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SVAS BIOSANA SPA

Eng. Giovanna Angelillo
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Somma V.na, October 2, 2023



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