



SVAS BIOSANA

EU DECLARATION OF CONFORMITY

UNI CEI EN ISO/IEC 17050-1:2010

**ACCORDING TO ANNEX II and III
of REGULATION (UE) 2017/745**



| | |
|-----------------------------|--|
| Manufacturer | SVAS BIOSANA SPA |
| Administrative Headquarters | Via Trentola, 7 80049 Somma Vesuviana (NA) - Italia |
| Medical device | Absorbent Underpad |
| Model | FARMEX |
| Class | I (according to rule 1 of Annex VIII of Regulation (UE) 2017/745 and following amendments) |
| CND Code | T04010202 |
| Lot | 21 WW (YY=Year, WW=Week) |
| Catalogue Code (REF) | 03JOL5003040 |
| Basic UDI-DI | 800400703JOL5003040CW |

The undersigned SVAS BIOSANA SPA **declares**, under its own responsibility, that the above-mentioned devices meet all the provisions of the Regulation (UE) 2017/745.

**Harmonized Standards and Common Specifications
used for the Declaration of Conformity**

EN ISO 13485 ; EN ISO 14971 ; EN1041 ;
EN ISO 15223-1 ; EN ISO 16021

Moreover, Svas Biosana SpA **declares** as following:

- The concerned devices meet the essential requirements as according to Annex I of the Regulation (EU) 2017/745.
- The concerned devices are sold in a NON-STERILE packaging;
- The concerned devices don't have A MEASURING FUNCTION;
- The concerned devices are NOT DESTINED FOR CLINICAL INVESTIGATION;
- The manufacturer undertakes to maintain and make available to the Competent Authority the technical documentation specified in Annex II of Regulation (EU) 2017/745 for a period of at least ten years from the date of manufacture of the last batch produced.

On behalf of SVAS BIOSANA SPA

Eng. Mario loele

Somma Vesuviana (NA), Italy 15.06.2021



Adult incontinence devices



Indice

| | |
|---|---|
| About SVAS BIOSANA | 2 |
| About FARMEX Division | 4 |
| Product Identification Guide | 6 |
| Features and benefits of Farmex incontinence products | 7 |

Farmex Standard Products

| | |
|-------------------------------|----|
| Adult Diaper | 8 |
| Shaped Diaper | 9 |
| Rectangular Pad | 9 |
| Absorbent Underpad | 10 |
| Elastic Panties | 10 |
| Lady Light Incontinence | 11 |
| Man Light Incontinence | 11 |

Farmex Premium Products.....12

| | |
|--|----|
| Premium Classic and Air Soft Dermo Diapers | 13 |
|--|----|

Farmex Air Products (breathable)

| | |
|-------------|----|
| Pants | 14 |
| Belt | 14 |

Body Wash

| | |
|------------------------|----|
| Soft wipes | 15 |
| Fluff wipes | 16 |
| Bibs with pocket | 16 |
| Soap Washcloth | 16 |

About Svas Biosana



SVAS BIOSANA S.p.A.

was founded in 1972 as a distribution company, specialized in medical device supplies. The company constantly grew up during the early years and quickly became an important point of reference in healthcare industry both on the domestic market and the overseas one. Later, the skills, necessary to carry its own goods production out, were got and the manufacturing strategy was developed. This project was realized by the establishment





of industrial divisions responsible for each different product line. The "Research & Development" Chemical Laboratory was settled up in 2002 and there is a team of specialists that studies and tests new materials and products. Nowadays **Svas Biosana S.p.A.** boasts a solid Quality Management System, complying with ISO 9001 and 13485 standards. It has got a multi-divisional structure which exalts the specialization of each operating area:

• Svas Division

• Farmex Division

• Medical Division

About Farmex Division

The division has been providing an effective solution for incontinence issues for more than 30 years.

The line of Adult Incontinent Aids includes a wide range of functional and safe devices for every grade of incontinence.

Thanks to the up-to-date technologies and the accurate selection of raw materials, Farmex products fulfil the needs and the expectations of its customers.



Quality and Certificates

Today Farmex Div. boasts a solid Quality Management System, complying with UNI EN ISO 9001: 2008 and UNI CEI EN ISO 13485: 2004 standards. All devices comply with the requirements of Directive 93/42/CEE and s.m.i. and are periodically tested by accredited laboratories.

SVAS BIOSANA follows the goals of:

- Full customer satisfaction;
- Management results improvement;
- Market competitiveness;
- Constant and continuous improvement of product quality and quality system.

The company's quality system guarantees an accurate selection of suppliers and raw materials. On the other hand, full customer satisfaction is achieved due to a constant attention to his needs.



Product Identification Guide

Farmex Incontinence Devices

FARMEX
Standard products

FARMEX PREMIUM
Breathable with
Derma-protection products

FARMEX AIR
Breathable products

(Grade of incontinence)

Absorbency level

Farmex proposes 4 different absorbency levels, identified by:
Name (A), Code Color (B), Drops number (C).

| | PLUS | EXTRA | SUPER | MAXI |
|---|----------|----------------|-------|------------|
| A | | | | |
| B | | | | |
| C | | | | |
| | moderate | medium / heavy | heavy | very heavy |

Sample pack



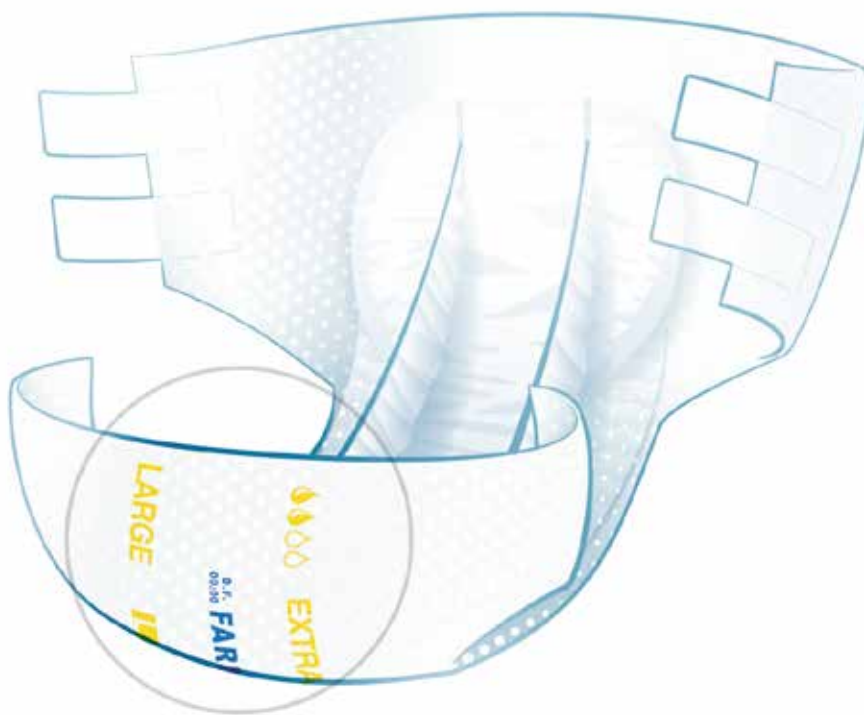
FARMEX

Features and benefits of Farmex incontinence products

The attention towards the care of elderly providing the product for patients' specific needs has helped the development and the production of an adult diaper with printed PE film for easy absorbency level identification. In fact, the product new identification system according to absorbency level is easy to use for both patients and nursing staff. Four different absorbency levels are detectable by the colour code system and the drops number.

Wording on the adult diaper gives the additional information:

- a) **Colour:** Absorbency Level
- b) **Text and drops number:** Size and absorbency level
- c) **Moisture indicator:** as soon as the lot and production date ink bleaches, the diaper must be changed.



Our adult incontinence devices are:

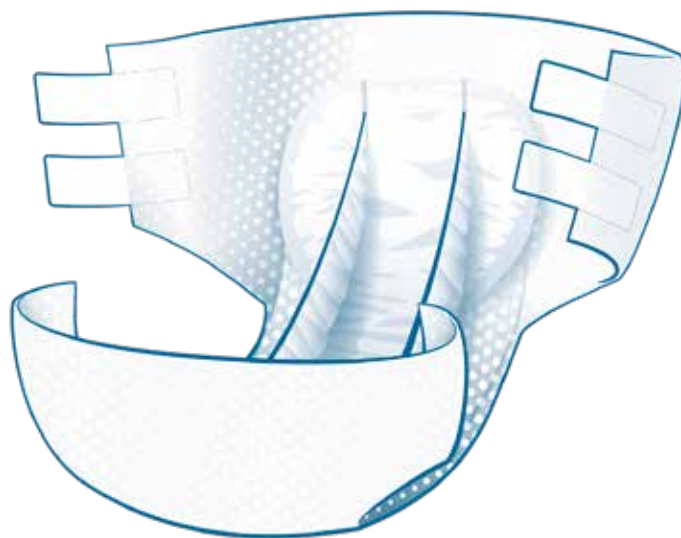
- Hypoallergenic
- Clinically Tested
- Latex Free
- Odor control:
Reduces the risk of unpleasant odours.



Farmex® Adult Diaper

This device is suitable for the protection and care of people suffering moderate and heavy incontinence. It is anatomically shaped and has such a liquids barrier. Four repositionable tapes and elastics around the legs help the device to keep the shape of panties while worn. The back-sheet is made of soft non-toxic waterproof polyethylene completed with a moisture local indicator for an easier product identification. The absorbent core is made of pure cellulose fluff and superabsorbent polymers (S.A.P.). It is covered by a special non-woven filter which accelerates the distribution of liquids and helps the moisture lock. A layer of hypoallergenic non-woven fabric covers the whole inner surface.

(Suitable both for bedridden and non-self-sufficient people)



| Ref | Ean | Paraph. | Iso N.T.N | Size | Absorb. | Drops | Pcs/Pck | Pcs/Cart |
|--------------|---------------|-----------|-------------------|------|---------|-------|---------|----------|
| 03JOL3103020 | 8004007310324 | 931436808 | RIC. 09.30.04.006 | M | PLUS | | 30 | 90 |
| 03JOL3103030 | 8004007310331 | 931436834 | RIC. 09.30.04.003 | L | | | 30 | 90 |
| 03JOL3201510 | 8004007320019 | 931436846 | 09.30.04.009 | S | EXTRA | | 15 | 150 |
| 03JOL3201520 | 8004007320023 | 941182343 | 09.30.04.006 | M | | | 15 | 90 |
| 03JOL3203020 | 8004007320323 | 931436911 | 09.30.04.006 | M | | | 30 | 90 |
| 03JOL3201530 | 8004007320033 | 941182329 | 09.30.04.003 | L | | | 15 | 90 |
| 03JOL3203030 | 8004007320330 | 931436935 | 09.30.04.003 | L | | | 30 | 90 |
| 03JOL3203040 | 8004007320347 | 931436947 | RIC. 09.30.04.003 | XL | | | 30 | 90 |
| 03JOL3301520 | 8004007330025 | 941182370 | RIC. 09.30.04.006 | M | SUPER | | 15 | 90 |
| 03JOL3303020 | 8004007330322 | 932229824 | RIC. 09.30.04.006 | M | | | 30 | 90 |
| 03JOL3301230 | 8004007330735 | 941182356 | RIC. 09.30.04.003 | L | | | 12 | 72 |
| 03JOL3303030 | 8004007330339 | 932229836 | RIC. 09.30.04.003 | L | | | 30 | 90 |
| 03JOL3302440 | 8004007330544 | 931437002 | RIC. 09.30.04.003 | XL | | | 24 | 72 |
| 03JOL3402220 | 8004007340420 | 931437038 | RIC. 09.30.04.006 | M | MAXI | | 22 | 66 |
| 03JOL3402230 | 8004007340437 | 931437040 | RIC. 09.30.04.003 | L | | | 22 | 66 |

IN PHARMACY

Farmex® Shaped Diaper

This device is destined to people with a light and moderate incontinence. It has an anatomical shape and liquids barrier, coupled with separate fastening system guarantees an exceptional wearability and use practicality. The backsheet is made of soft non-toxic waterproof polyethylene completed with a humidity indicator for an easier product identification. The absorbent core is made of pure cellulose fluff and superabsorbent polymers (S.A.P.). It is covered by a special non-woven filter which accelerates the distribution of liquids and helps the moisture lock. A layer of hypoallergenic non-woven fabric covers the whole inner surface.

(Suitable both for bedridden and walking people.)



| Ref | Ean | Paraph | N.T.N. | Absorb. | Drops | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|-----------|-------------------|---------|-------|----------|-----------|
| 03JOL2102000 | 8004007210204 | 931093468 | 09.30.04.018 | PLUS | 💧💧💧 | 20 | 80 |
| 03JOL2202000 | 8004007220203 | 931093470 | 09.30.04.015 | EXTRA | 💧💧💧 | 20 | 80 |
| 03JOL2302000 | 8004007230202 | 931093482 | 09.30.04.012 | SUPER | 💧💧💧 | 20 | 80 |
| 03JOL2402000 | 8004007240201 | 931093494 | RIC. 09.30.04.012 | MAXI | 💧💧💧 | 20 | 80 |

Farmex® Rectangular Pad

This device is suitable for protection and care of people with moderate incontinence. It has a rectangular shape and is available in 2 versions, with and without liquids barrier. Together with plastic or elastic mesh panties the device guarantees an excellent use practicality. In the liquid barrier version, the backsheet is made of soft non-toxic waterproof polyethylene. The absorbent core is made of pure cellulose fluff, evenly distributed and firmly incorporated into the inner layer, composed of hypoallergenic non-woven fabric to get the utmost compactness. The whole structure guarantees an efficient moisture lock. The barrier-free type can be used inside panty diapers in cases of severe incontinence in order to increase its performances.

(Suitable for bedridden and walking people.)



| STANDARD | | | | | | | | |
|--------------|---------------|-----------|--------------|-----------------|---------|-------|----------|-----------|
| Ref | Ean | Paraph | Iso N.T.N. | Type | Assorb. | Drops | Pcs/Pack | Pcs/Cart. |
| 03JOL4103001 | 8004007410307 | 931437077 | 09.30.04.021 | with barrier | PLUS | 💧💧💧 | 30 | 180 🏠 |
| 03JOL4103000 | 8004007410314 | 931437103 | 09.30.04.021 | without barrier | | | 30 | 180 🏠 |

🏠 IN PHARMACY

Farmex® Absorbent Underpad

The device is suitable for bedridden patients in case of urinary and fecal incontinence. Positioned between the patient and the bed for maximum hygiene, it is not wearable. The outer side is made of soft non-toxic waterproof polyethylene. The absorbent core is made of pure cellulose fluff, evenly distributed and firmly incorporated into the top layer, made of hypoallergenic non-woven fabric, for maximum compactness. The whole structure guarantees an efficient moisture lock.



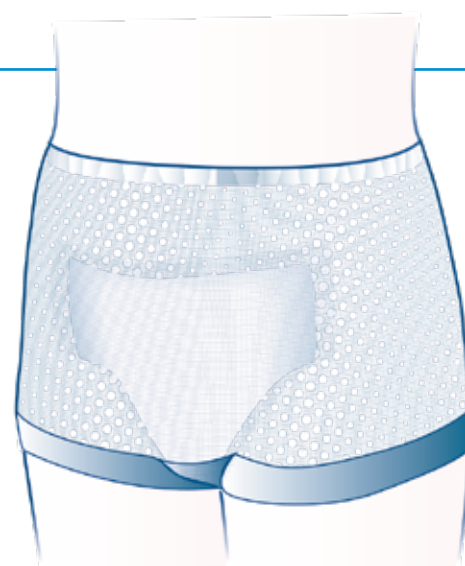
| STANDARD | | | | | | |
|--------------|---------------|-----------|-------------------|------------|----------|-----------|
| Ref | Ean | Paraph | Iso N.T.N | Size | Pcs/Pack | Pcs/Cart. |
| 03JOL5001510 | 8004007500015 | 931437519 | RIC. 18.12.15.006 | 40 X 60 | 15 | 90 |
| 03JOL5003020 | 8004007500329 | 931437533 | RIC. 18.12.15.006 | 60 X 60 | 30 | 90 |
| 03JOL5001530 | 8004007500039 | 941182406 | 18.12.15.006 | 60 X 90 | 15 | 90 + |
| 03JOL5003030 | 8004007500336 | 931437560 | 18.12.15.006 | 60 X 90 | 30 | 90 |
| 03JOL5001540 | 8004007500046 | 941182394 | 18.12.15.003 | 80 X 180 * | 15 | 90 + |
| 03JOL5003040 | 8004007500343 | 931437584 | 18.12.15.003 | 80 X 180 * | 30 | 90 |

| ULTR | | | | | | |
|--------------|--------------|-----------|-------------------|-----------|----------|-----------|
| Ref | Ean | Paraph | N.T.N. | Size | Pcs/Pack | Pcs/Cart. |
| 03JOL5023030 | 03JOL5103030 | 932230170 | RIC. 18.12.15.006 | 60 X 90 | 30 | 90 |
| 03JOL5023040 | 03JOL5103040 | 932230182 | RIC. 18.12.15.003 | 80 X 180* | 30 | 90 |

+ IN PHARMACY * FOLDABLE

Farmex® Elastic Panties

This product is suitable to hold diapers (rectangular, shaped) or wound care devices such as gauze or nonwoven pads "in situ". Due to its elasticity it can keep stable and adherent the absorbent pads in the ideal position, without compressing on. It is washable at 60°C as well as reusable for several times.

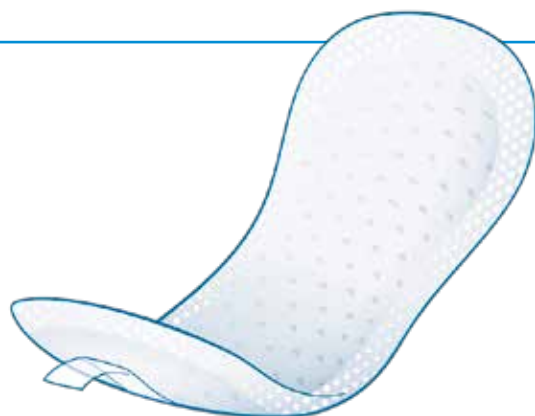


| Ref | Ean | Paraph | N.T.N. | Size | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|-----------|-------------------|------------|----------|-----------|
| 03JOL9600310 | 8004007960017 | 932230131 | 09.30.09.009 | SMALL | 30 x 3 | 90 |
| 03JOL9600320 | 8004007960024 | 932230143 | 09.30.09.006 | MEDIUM | 30 x 3 | 90 |
| 03JOL9600330 | 8004007960031 | 932230156 | 09.30.09.003 | LARGE | 30 x 3 | 90 |
| 03JOL9600340 | 8004007960048 | 932230168 | RIC. 09.30.09.003 | EXTRALARGE | 30 x 3 | 90 |

Farmex® Lady

This diaper is designed to guarantee a considerable absorbency together with a suitable solution for a light incontinence issue. The soft multi-layer filter distributes the liquids uniformly along the entire surface and it always keeps dry the skin. The absorbent core is made of cellulose fluff mixed with super-absorbent polymers. There is a longitudinal adhesive and an innovative "OdorFree" system to prevent unpleasant odours. Normal, Extra and Super formats are individually packed in practical hygienic sachets.

(Suitable for people with light and moderate incontinence issue.)



| Ref | Ean | Paraph | Iso N.T.N | Absorb. | Drops | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|-----------|-------------------|------------|-------|----------|-----------|
| 03JOL2001210 | 8004007200700 | 932229848 | RIC. 09.30.04.018 | NORMAL | | 12 | 144 |
| 03JOL2001020 | 8004007200113 | 932229851 | RIC. 09.30.04.018 | EXTRA | | 10 | 120 |
| 03JOL2001030 | 8004007200120 | 932229875 | RIC. 09.30.04.018 | SUPER | | 10 | 120 |
| 03JOL2001440 | 8004007200830 | 932229899 | RIC. 09.30.04.018 | SUPER PLUS | | 14 | 168 |

IN PHARMACY

Farmex® Man

It is a physio-anatomical aid specifically designed for light male incontinence. An adhesive pattern allows to fix it to normal briefs. Farmex Men is very easy to use due to its extremely small size and its shape which ensures safety to the wearer.



| Ref | Ean | PARAF | Iso N.T.N | Assorb. | Pezzi | Imballi |
|--------------|---------------|-----------|-------------------|---------|-------|---------|
| 03JOL9041200 | 8004007904004 | 941182418 | RIC. 09.30.04.018 | LIV. 1 | 12 | 96 |
| 03JOL9051000 | 8004007905001 | 941182432 | RIC. 09.30.04.018 | LIV. 2 | 10 | 80 |

IN PHARMACY

New breathable diaper

FARMEX offers you a new **Premium** diaper, an innovative customized solution for the needs of patients and nursing staff.

The wings, made of non-woven fabric, provide high breathability for the right oxygenation of the skin consequently limiting the risk of irritation.

The sola central section of the backsheet can be made of polyethylene for the **Classic** version or breathable non-woven fabric for the **Air Soft Dermo** version. It keeps liquids away from the skin and at the same time guarantees high breathability and rash reduction on particularly sensitive skin.

Two absorbent equal sized cushions, **composed of 100% PEFC** certified long-fiber conifer cellulose fluff, form the intermediate layer of the device, its core. The cushions confer three-dimensional structure to the core and ensure quicker acquisition of liquids by the device.

Furthermore, a special **super absorbent polymer (S.A.P.)**, the sodium polyacrylate, was added to the fluff in order to increase absorbent capacity and manage unpleasant odor.

The central section of the absorbent cushion is covered by the **A.D.L. (Acquisition Distribution layer)**, a special non-woven filter which accelerates the distribution of liquids across the absorbent surface, improving further both the absorbency and the moisture lock.

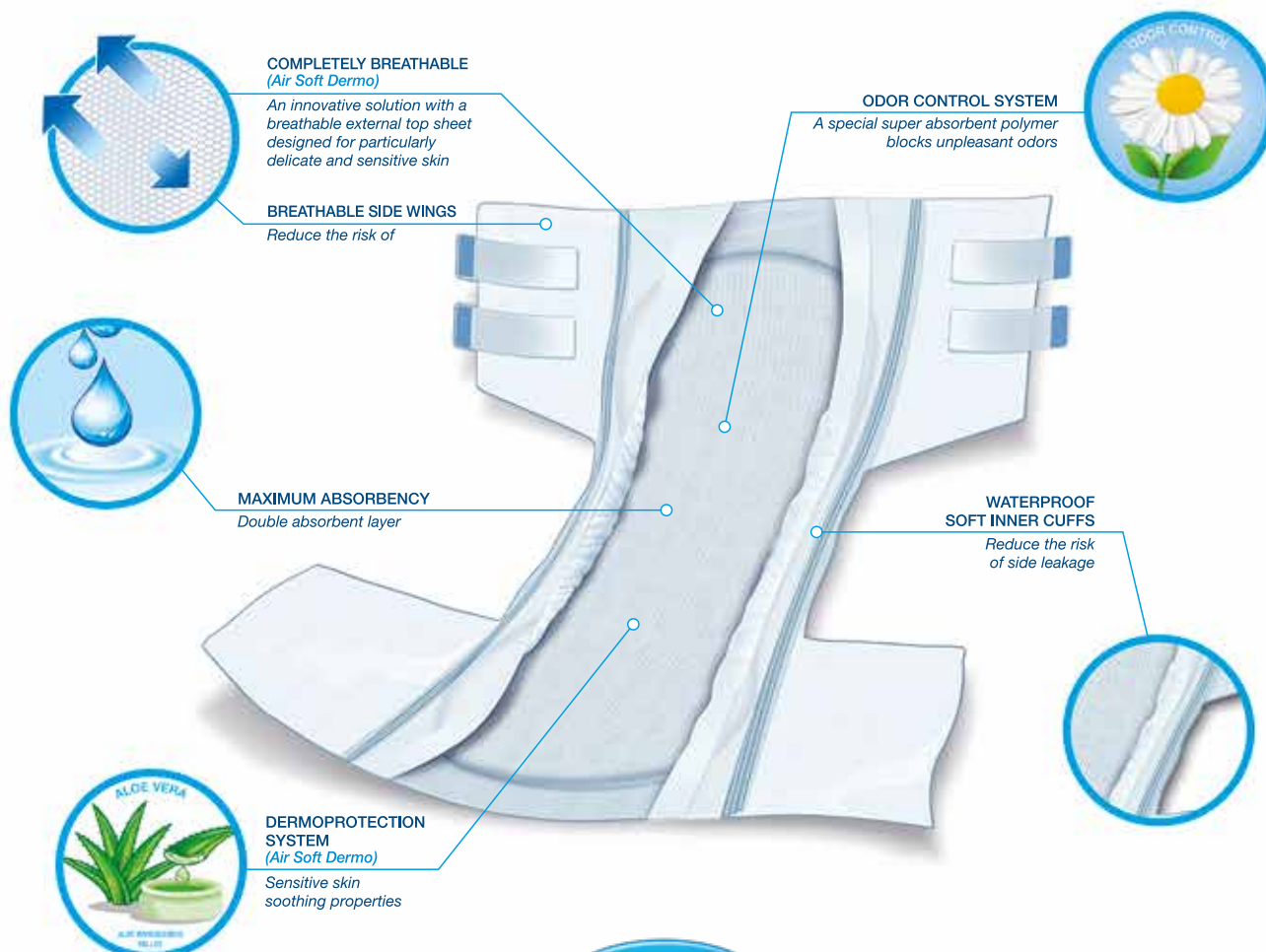
The internal layer of the device which comes into contact with the patient's skin, the topsheet, is made of non-woven fabric composed of polypropylene fibre. Due to its osmotic characteristics it allows an effective permeability to liquids and at the same time prevents their spilling out, significantly reducing the release of moisture.

For the **Air Soft Dermo version**, the topsheet is treated with a skin-care aloe vera lotion that gives the device soothing, moisturizing and antiseptic properties for sensitive skin protection.

Soft inner cuffs across the entire length of the topsheet are made of special hydrophobic non-woven fabric (SMS - Spunbond Meltblown Spunbond). Supported by two elastics each which reduce the risk of side leakage even if the patient is turned on the side.

Four stretch side panels made of water-repellent breathable non-woven fabric, two of which are fixed with two tapes each, thereby permitting the wearability of the device, which is also guaranteed by the presence of filiform polyurethane latex free elastics around the legs.

The device is dermatologically tested, hypoallergenic, non-toxic and **LATEX FREE**.



PREMIUM

coming soon

ADULT DIAPERS - CLASSIC

| ART CODE | DESCRIPTION | Pcs/Pck | Pcs/Crt | EAN | N.T.N. |
|--------------|--|---------|---------|---------------|----------------|
| 03JOL3223010 | PREMIUM CLASSIC ADULT DIAPERS EXTRA (30 PCS.) SMALL | 30 | 4 | 8004007322310 | 09.30.21.009 |
| 03JOL3223020 | PREMIUM CLASSIC ADULT DIAPERS EXTRA (30 PCS.) MEDIUM | 30 | 4 | 8004007322327 | 09.30.21.006 |
| 03JOL3223030 | PREMIUM CLASSIC ADULT DIAPERS EXTRA (30 PCS.) LARGE | 30 | 4 | 8004007322334 | 09.30.21.003 |
| 03JOL3223040 | PREMIUM CLASSIC ADULT DIAPERS EXTRA (30 PCS.) EXTRA LARGE | 30 | 4 | 8004007322341 | R 09.30.21.003 |
| 03JOL3323020 | PREMIUM CLASSIC ADULT DIAPERS SUPER (30 PCS.) MEDIUM | 30 | 4 | 8004007332326 | 09.30.21.015 |
| 03JOL3323030 | PREMIUM CLASSIC ADULT DIAPERS SUPER (30 PCS.) LARGE | 30 | 4 | 8004007332333 | 09.30.21.012 |
| 03JOL3322440 | PREMIUM CLASSIC ADULT DIAPERS SUPER (24 PCS.) EXTRA LARGE | 30 | 4 | 8004007332548 | R 09.30.21.012 |
| 03JOL3423020 | PREMIUM CLASSIC ADULT DIAPERS MAXI (30 PCS.) MEDIUM | 30 | 4 | 8004007342325 | R 09.30.21.015 |
| 03JOL3423030 | PREMIUM CLASSIC ADULT DIAPERS MAXI (30 PCS.) LARGE | 30 | 4 | 8004007342332 | R 09.30.21.012 |
| 03JOL3422440 | PREMIUM CLASSIC ADULT DIAPERS MAXI (24 PCS.) EXTRA LARGE | 24 | 4 | 8004007342547 | R 09.30.21.012 |

ADULT DIAPERS - AIR SOFT DERMO

| ART CODE | DESCRIPTION | Pcs/Pck | Pcs/Crt | EAN | N.T.N. |
|--------------|---|---------|---------|---------------|----------------|
| 03JOL3243010 | PREMIUM AIR SOFT DERMO ADULT DIAPERS EXTRA (30 PCS.) SMALL | 30 | 4 | 8004007324314 | 09.30.21.009 |
| 03JOL3243020 | PREMIUM AIR SOFT DERMO ADULT DIAPERS EXTRA (30 PCS.) MEDIUM | 30 | 4 | 8004007324321 | 09.30.21.006 |
| 03JOL3243030 | PREMIUM AIR SOFT DERMO ADULT DIAPERS EXTRA (30 PCS.) LARGE | 30 | 4 | 8004007324338 | 09.30.21.003 |
| 03JOL3243040 | PREMIUM AIR SOFT DERMO ADULT DIAPERS EXTRA (30 PCS.) LARGE | 30 | 4 | 8004007324345 | R 09.30.21.003 |
| 03JOL3343020 | PREMIUM AIR SOFT DERMO ADULT DIAPERS SUPER (30 PCS.) MEDIUM | 30 | 4 | 8004007334320 | 09.30.21.015 |
| 03JOL3343030 | PREMIUM AIR SOFT DERMO ADULT DIAPERS SUPER (30 PCS.) LARGE | 30 | 4 | 8004007334337 | 09.30.21.012 |
| 03JOL3342440 | PREMIUM AIR SOFT DERMO ADULT DIAPERS SUPER (24 PCS.) EXTRA LARGE | 24 | 4 | 8004007334542 | R 09.30.21.012 |
| 03JOL3443020 | PREMIUM AIR SOFT DERMO ADULT DIAPERS MAXI (30 PCS.) MEDIUM | 30 | 4 | 8004007344329 | R 09.30.21.015 |
| 03JOL3443030 | PREMIUM AIR SOFT DERMO ADULT DIAPERS MAXI (30 PCS.) LARGE | 30 | 4 | 8004007344336 | R 09.30.21.012 |
| 03JOL3442440 | PREMIUM AIR SOFT DERMO ADULT DIAPERS MAXI (24 PCS.) EXTRA LARGE | 24 | 4 | 8004007344541 | R 09.30.21.012 |

Farmex® Pants

A disposable fully breathable absorbent pant which can be worn like a normal underwear, it provides comfort and free movements. Elastic soft sides allow to wear the pants in total comfort. The pants are made of an absorbent pattern made of cellulose fluff mixed with the super-absorbent polymers, and the innovative "Odours Control System" to reduce the unpleasant odours.

(Suitable for patients suffering from a medium to severe incontinence)



| Ref | Ean | Paraph | N.T.N. | Size | Absorb. | Drops | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|-----------|-------------------|------|---------|-------|----------|-----------|
| 03JOL8201410 | 8004007820816 | 932230067 | RIC. 09.30.04.003 | S | EXTRA | | 14 | 84 |
| 03JOL8201420 | 8004007820823 | 932230093 | RIC. 09.30.04.003 | M | | | 14 | 84 |
| 03JOL8201430 | 8004007820830 | 932230117 | RIC. 09.30.04.003 | L | | | 14 | 84 |
| 03JOL8201440 | 8004007820847 | 932230129 | RIC. 09.30.04.003 | XL | | | 14 | 84 |

FARMEX AIR line provides air circulation preventing the cutaneous complications. Moreover, new products guarantee high level comfort due to their softness and rustle absence.



Farmex® Belt

A completely breathable device. Velcro closure fastening system guarantees maximum comfort and excellent fitting; it allows the patient to fasten the diaper autonomously with no extra help. It is easier and faster to change rather than traditional diapers.

(Ideal for people with moderate and severe incontinence issue.)



| Ref | Ean | Paraph | Iso N.T.N | Size | Absorb. | Drops | Pcs/Pck | Pcs/Cart. |
|--------------|---------------|-----------|-------------------|------|---------|-------|---------|-----------|
| 02JOL6122510 | 8004007070082 | 939267896 | RIC. 09.30.04.009 | S | EXTRA | | 25 | 75 |
| 02JOL6122520 | 8004007070099 | 939267959 | RIC. 09.30.04.006 | M | | | 25 | 75 |
| 02JOL6122530 | 8004007070105 | 939268001 | RIC. 09.30.04.003 | L | | | 25 | 75 |
| 02JOL6122540 | 8004007070112 | 941598359 | RIC. 09.30.04.003 | XL | | | 25 | 75 |

Higiene wipes

The Adult Hygiene wipes are ideal for aged people with thin and delicate skin especially when exposed to irritants. Suitable for easy and quick daily hygiene, including cases of walking difficulties and incontinence.

It removes impurities avoiding rinsing, it gently cleanse leaving the skin soft and smooth and providing such a pleasant freshness sensation. Large dimensions make extremely easy to use them.



NO ALCOHOL
HYPOALLERGENIC

NO RINSE OFF WITH WATER IS REQUIRED AFTER USE.
MICROWAVE HEATING.

Extra Large and Soft wipes particularly indicated for bedridden patients during the diaper change.

Special formula with Vitamin E (Antioxidant, physiological pH)
Chamomile and Cornflower Extracts (regenerating, calming and soothing properties).
Enriched with natural Bisabolol (Refreshing, cleansing and moisturizing)

particularly
suitable for



Bedridden



Changing diapers

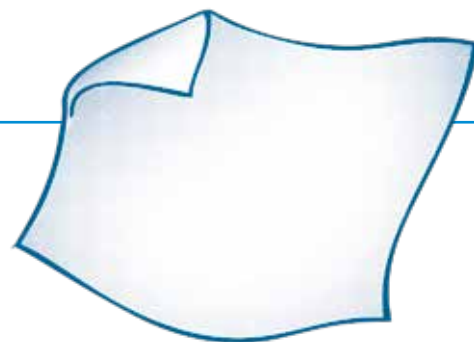
| Ref | Ean | Size | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|---------|----------|-----------|
| 03JOL9100240 | 8004007910005 | 20 x 30 | 24 | 12 X 24 |



Fluff Wipes

Disposable multi-purpose soft wipes with high absorption for gentle cleansing and drying. Made of pure cellulose fluff, extremely resistant, can be used both dry and wet.

(Wet with warm water; use with a small quantity of cleansing lotion or lightly moistened for gentle refreshing.)



| Ref | Ean | Size | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|------------|----------|-----------|
| 03JOL9111000 | 8004007911002 | 30 x 40 cm | 100 | 12 X 100 |

Bibs with pocket

Have a practical pocket and comfortable anti-strangle laces. The product is made of soft polyethylene combined with a layer of pure absorbent cellulose.



| Ref | Ean | Size | Pcs/Pack | Pcs/Cart. |
|--------------|---------------|------------|----------|-----------|
| 03JOL9121500 | 8004007912009 | 48 x 68 cm | 150 | 6 X 150 |

Soap Washcloth

Made of soft polyester, it has a series of thin parallel lines of dry neutral pH soap on the surface. Disposable and easy to be used, it does not irritate the patient's skin, prevents infections that might be caused by traditional sponge use. The soap detergent function is activated by a few water drops forming such a soft foam. After washing the patient, it is possible to remove the exceeding foam by using a practical paper towel.



| Ref | Pcs/Pack | Pcs/Cart. |
|--------------|----------|-----------|
| 7SVAS9007210 | 50 | 20 X 50 |





SVAS BIOSANA S.p.A.

Via Trentola, No. 7 - 80049 Somma Vesuviana
Naples, Italy
Phone: +39 081 8995411

www.svas.it
export@svas.it



SVAS BIOSANA

DECLARATION OF EC CONFORMITY

UNI CEI EN ISO/IEC 17050-1:2010

**ACCORDING TO ANNEX VII
(directive 93/42/CEE and following amendments)**



Manufacturer

SVAS BIOSANA SPA

Administrative Headquarters

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

Medical device

Absorbent Underpad

Model

FARMEX

Class

I (according to annex IX of Directive 93/42/EEC and following amendments)

CND Code

T04010102

Lot

YYWW (YY=Year, WW=Week)

Catalogue Code

03JOL500PPSS

(PP=Pieces/bag; SS=Size:10=40x60, 20=60x60, 30=60x90, 40=80x180)

The undersigned SVAS BIOSANA SPA **declares**, under its own responsibility that the above-mentioned devices meet all the provisions of the directive 93/42/ EEC and following amendments.

Certified Quality System

UNI EN ISO 9001:2015; UNI EN ISO 13485:2012

Moreover, Svas Biosana SpA **declares** as following:

- 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 NON-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 VII 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. Mario loele

Somma Vesuviana (NA), Italy
01.12.2020

| | | | | |
|--|--------------------|-------------|---|--|
|  SVAS BIOSANA | | | FARMEX ABSORBENT INCONTINENCE AIDS | |
| Data Emissione | Aggiornamento | | | |
| 16.04.2012 | Data 18.06.2012 | Indice 1 | TECHNICAL REPORT N. 143-002 | |

UNDERPAD



The device is manufactured for all the cases of urinary and fecal incontinence for bedridden patients. It is not wearable, this device may be positioned between the patient and the bed surface in order to ensure the health of people. The external side is made of soft, non-toxic and waterproof polyethylene. The absorption area is composed of pure fluff pulp, evenly and firmly distributed onto the roof to make everything compact. The hypoallergenic non-woven inner layer covers the entire surface. Its structure helps an efficient retention of the liquids.

TECNICAL AND LOGISTIC DETAILS

| | | | | | |
|----------------|--|---------------|---------------|---------------|---------------|
| Size | | 80*180 cm | 60*90 cm | 60*60 | 40*60 |
| Code Article | | 03JOL5003040 | 03JOL5003030 | 03JOL5003020 | 03JOL5001510 |
| Colour Article | | White | White | White | White |
| Code EAN | | 8004007500343 | 8004007500336 | 8004007500329 | 8004007500015 |

| | | | | | |
|---------------------------|-------------------|----------|---------|---------|---------|
| Total Dimension | cm. | 80 x 180 | 60 x 90 | 60X60 | 40X60 |
| Absorbent Total Dimension | cm. | 55 x 76 | 55 x 86 | 55 x 55 | 35 x 55 |
| Absorbent Total Dimension | cm ² . | 4.180 | 4.730 | 3025 | 1925 |

| | | | | | |
|------------------|----|------|------|-------|-------|
| Total Weight | g. | 71 | 75 | 50 | 35 |
| Cellulose Weight | g. | 40.7 | 55.3 | 36.64 | 25.65 |

| | | | | | |
|-----------------------------------|-----|-------|-------|-----|-----|
| Absorption Capacity (ISO 11948-1) | ml. | 1.350 | 1.540 | 950 | 600 |
|-----------------------------------|-----|-------|-------|-----|-----|

| | | | | | |
|--------------------|------|-------------|-------------|-------------|-------------|
| Bag | pcs. | 30 | 30 | 30 | 15 |
| Carton | pcs. | 3 | 3 | 3 | 6 |
| Carton Dimension | mm. | 595x395x210 | 595x395x230 | 595x395x210 | 590x320x220 |
| Cartons per pallet | pcs. | 32 | 32 | 32 | 28 |
| Layers per pallet | | 8 | 8 | 8 | 7 |

SVAS BIOSANA
S.p.A.

Registro Imprese
Trib. Napoli n.4543/85
C.F. 04720630633
Partita IVA 01354901215

Sede Legale
Via M. Perillo, 34
80047 S. G. Vesuviano (NA)
ITALIA

Direzione ed Uffici
Via Trentola
80049 Somma Ves. (NA)
ITALIA

Stabilimento
Via Colle, 104
80049 Somma Ves. (NA)
ITALIA

Telefono 0039.081.8931992

Fax 0039.081.8931807

CERTIFICATO N° 442SGQ11

CERTIFICATE N° 442SGQ11

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

SVAS BIOSANA S.p.A.

Via M. Perillo, 34 - IT 80047 SAN GIUSEPPE VESUVIANO (NA)

Nelle Strutture Operative di cui in allegato 1 al presente Certificato e per le attività elencate

In the Operative Units as per Annex 1 of this Certificate and for the indicated activities

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi

concerning the following kinds of Processes

Progettazione e produzione di dispositivi medici:

sistemi e kit completi per campo operatorio, teli e accessori per campo operatorio,
dispositivi di somministrazione compresi gli aghi spinali, prelievo e sistemi completi per l'aspirazione chirurgica,
dispositivi per apparato urogenitale, ovatta e cotone idrofilo.

Progettazione, produzione, distribuzione anche a domicilio di dispositivi medici:

dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni standard e specialistiche.

Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici.

Erogazione di servizi di relazione con il cliente, il consumatore ed il cittadino, attraverso centri di contatto, compresi Call Center.

Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione.

Commercializzazione di dispositivi medici non attivi e non impiantabili, presidi medico chirurgici,
medicinali per uso umano e veterinario, articoli sanitari vari e cosmetici.

*Design and production of medical devices: complete systems and kits for the operating field, towels and accessories for the operating field,
administration devices including spinal needles and complete systems for surgical suction, devices for urogenital apparatus, wadding and hydrophilic cotton wool.
Design, production and distribution, even at home, of medical devices: protection devices and incontinence aids, devices for standard and specialist dressings.*

Design and provision of home care services for the supply of medical devices.

Provision of relationship services with the customer, the consumer and the citizen, through contact centers, including call centers.

Design and provision of the service for the management and operation of sterilization centers.

Marketing of non active non implantable medical devices, medical-surgical devices, medicines for human and veterinary use, various sanitary articles, and cosmetics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la Certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rule for the certification in force applicable.

Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1

This Certificate should be made public only in integral form complete Annex 1

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In case of discrepancies between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione

First Issue Date

2003-02-27

Data di Prima Emissione ITALCERT

First Issue Date ITALCERT

2009-10-12

Data di Rinnovo

Renewal Date

2020-12-19

Data di Scadenza

Expiration Date

2023-12-18

Settore IAF 14 - 29 - 35 - 04 - 17



SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Allegato 1 al Certificato n° 442SGQ11
Annex 1 of Certificate 442SGQ11

| Unità | Indirizzo Sede | Oggetto |
|-----------------------------|--|--|
| FARMEX | Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA | <p>Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni standard e specialistiche.</p> <p>Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici.</p> <p>Erogazione di servizi di relazione con il cliente, il consumatore ed il cittadino, attraverso centri di contatto, compresi Call Center.</p> <p>Progettazione e produzione di dispositivi medici: ovatta di cotone idrofilo.</p> <p>Produzione di articoli sanitari vari.</p> <p><i>Design, production and distribution, even at home, of medical devices: protective devices and incontinence aids; devices for standard and specialist dressings. Design and provision of home care services and after-sales services for the supply of medical devices. Provision of relationship services with customers, consumers and citizens, through contact centers, including Call Center.</i></p> <p><i>Design and production of medical devices: hydrophilic cotton wool. Production of various sanitary.</i></p> |
| SVAS | <p>Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA</p> <p>Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA</p> | <p>Commercializzazione di dispositivi medici: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni standard e specialistiche, dispositivi di protezione e ausili per incontinenza.</p> <p>Commercializzazione di presidi medico-chirurgici, preparati galenici, medicinali per uso umano e veterinario, articoli sanitari vari e cosmetici.</p> <p><i>Marketing of medical devices: devices for administration, collecting and picking; protection devices and incontinence aids; devices for standard and specialist dressings. Marketing of medical-surgical supplies, galenic preparations, medicinal products for human and veterinary use, various sanitary articles and cosmetics.</i></p> |
| MEDICAL | <p>Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA</p> <p>Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA</p> | <p>Progettazione e produzione di dispositivi medici:</p> <p>sistemi e kit completi per campo operatorio, teli e accessori per campo operatorio, dispositivi per medicazioni standard e specialistiche, dispositivi di somministrazione compresi gli aghi spinali, prelievo e sistemi completi per l'aspirazione chirurgica, dispositivi per apparato urogenitale.</p> <p><i>Design and production of medical devices: systems and operating packs for surgery site, towels and accessories for surgery site, devices for standard and specialist dressings, devices for administration including spinal needles; complete systems for surgical aspiration, devices for urogenital apparatus.</i></p> |
| Centrale di Sterilizzazione | Ente Ospedaliero Regionale MIULLI Strada Provinciale, 127 IT 70021 Acquaviva delle Fonti BA | <p>Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione.</p> <p><i>Design and supply of management and conduction service for sterilization centre.</i></p> <p>TEMPORARY SITE: monitoring by ITALCERT</p> |

La validità del presente Allegato è vincolata a quella del Certificato N 442SGQ11

The validity of this Annex is bound to the Certificate N 442SGQ11

2020-12-19

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Settore IAF 14 – 29 – 35 – 04 – 17


SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

CERTIFICATO N° 442DM11

CERTIFICATE N° 442DM11

Si certifica che il

this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da

implemented by

SVAS BIOSANA S.p.A.

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

Nelle Strutture Operative di cui in allegato 1 al presente Certificato
e per le attività elencate

In the Operative Units as per Annex 1 of this Certificate and for the indicated activities

è conforme alla norma

is in compliance with the standard

UNI CEI EN ISO 13485-2016 (ISO 13485-2016)

per i seguenti Processi

concerning the following kinds of Processes

Progettazione e produzione di dispositivi medici:

sistemi e kit completi per campo operatorio, teli e accessori per campo operatorio,
dispositivi di somministrazione compresi gli aghi spinali, prelievo e sistemi completi per l'aspirazione chirurgica,
dispositivi per apparato urogenitale, ovatta e cotone idrofilo.

Progettazione, produzione, distribuzione anche a domicilio di dispositivi medici:

dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni standard e specialistiche.

Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici.

Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione

Commercializzazione di dispositivi medici non attivi e non impiantabili.

*Design and production of medical devices: complete systems and kits for the operating field, towels and accessories for the operating field,
administration devices including spinal needles and complete systems for surgical suction, devices for urogenital apparatus, wadding and hydrophilic cotton wool.*

Design, production and distribution, even at home, of medical devices: protection devices and incontinence aids, devices for standard and specialist dressings.

Design and provision of home care services for the supply of medical devices. Design and provision of the service for the management and operation of sterilization centers.

Marketing of non active non implantable medical devices

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la Certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rule for the certification in force applicable.

Il presente Certificato deve essere reso pubblico solo in forma integrale completo dell'Allegato 1

This Certificate should be made public only in integral form complete Annex 1

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In case of discrepancies between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione

First Issue Date

1997-06-23

Data di Prima Emissione ITALCERT

First Issue Date ITALCERT

2009-10-12

Data di Rinnovo

Renewal Date

2020-12-19

Data di Scadenza

Expiration Date

2023-12-18



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Allegato 1 al Certificato n° 442DM11
Annex 1 of Certificate 442DM11

| Unità | Indirizzo Sede | Oggetto |
|-----------------------------|---|---|
| FARMEX | Via Colle, 104 – IT 80049 SOMMA VESUVIANA NA | Progettazione, produzione e distribuzione, anche a domicilio, di dispositivi medici: dispositivi di protezione e ausili per l'incontinenza, dispositivi per medicazioni standard e specialistiche. Progettazione ed erogazione di servizi di assistenza domiciliare per la fornitura di dispositivi medici Progettazione e produzione di dispositivi medici: ovatta e cotone idrofilo. <i>Design, production and distribution, even at home, of medical devices: Protective devices and incontinence aids; devices for standard and specialist dressings. Design and provision of home care services for the supply of medical devices</i> <i>Design and production of medical devices: wadding and hydrophilic cotton wool</i> |
| SVAS | Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA | Commercializzazione di dispositivi medici non attivi non impiantabili: dispositivi da somministrazione, prelievo e raccolta, dispositivi per medicazioni standard e specialistiche, dispositivi di protezione e ausili per incontinenza. <i>Marketing of non active non implantable medical devices: devices for administration, collecting and picking; protection devices and incontinence aids; devices for standard and specialist dressings.</i> |
| MEDICAL | Via Trentola, 7 – IT 80049 SOMMA VESUVIANA NA Via Genio Militare, Località Pentelete – IT 80044 OTTAVIANO NA | Progettazione e produzione di dispositivi medici: sistemi e kit completi per campo operatorio, teli e accessori per campo operatorio, dispositivi per medicazioni standard e specialistiche, dispositivi di somministrazione compresi gli aghi spinali, prelievo e sistemi completi per l'aspirazione chirurgica, dispositivi per apparato urogenitale. <i>Design and production of medical devices: systems and operating packs for surgery site, towels and accessories for surgery site, devices for standard and specialist dressings, devices for administration including spinal needles; complete systems for surgical aspiration, devices for urogenital apparatus.</i> |
| Centrale di Sterilizzazione | Ente Ospedaliero Regionale MIULLI Strada Provinciale, 127 IT 70021 Acquaviva delle Fonti BA | Progettazione ed erogazione del servizio di gestione e conduzione di centrali di sterilizzazione. <i>Design and supply of management and conduction service for sterilization centre.</i> TEMPORARY SITE: monitoring by ITALCERT |

La validità del presente Allegato è vincolata a quella del Certificato N 442DM11

The validity of this Annex is bound to the Certificate N 442DM11

2020-12-19

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements