0.0 INTRODUCTION AND PURPOSE OF THE SUMMARY

To comply with article 32 of the European Regulation 745/2017, this document serves as a summary relating to the safety and clinical performance (SSCP) of the product mentioned below with the aim of making information on the safety and performance of the device publicly accessible.
The SSPC must be a source that contains important information for users (both professional users and information relevant to patients).
This document is drawn up for medical devices with risk class III or if it is an implantable device and subsequent must be validated by the notified body and published the European Database (Eudamed).
The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.
This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.
The following information is intended for users/healthcare professionals (doctors).
Following this information there is a summary intended for patients.

1.0 DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 - Device trade name	**ALGENESS LD, ALGENESS HD, ALGENESS VL, ALGENESS DF**
1.2 - Manufacturer	GHIMAS S.p.A. Via Domenico Cimarosa, 85, 40033 – Casalecchio di Reno, BO, Italy
1.3 - SRN Manufacturer	IT-MF-000017070.
1.4 - Basic UDI-DI	ALGENESS LD: 803357637ALGENESS10YU ALGENESS HD: 803357637ALGENESS15Z6 ALGENESS VL: 803357637ALGENESS25Z9 ALGENESS DF: 803357637ALGENESS35ZC
1.5 - Nomenclature CND and Description	P900402 - REABSORBABLE PRODUCTS FOR FILLING AND REBUILDING
1.6 - Class of device	III – Rule 8 of Annex VIII of the Regulation EUE 2017/745.
1.7 - Year of the first certificate (CE)	2004
1.8 - NB's name and the NB's single identification number	Eurofins Product Testing Italy Srl – number 0477

2.0 INTENDED USE

2.1 - Intended purpose	In the aesthetic field, Algeness is a resorbable filler indicated for the correction of skin imperfections caused by wrinkles, folds or sunken scars. In particular, the use of Algeness VL and DF is also specifically indicated for the correction of nasolabial wrinkles.
2.2 - Indications	Algeness may only be used by physicians qualified in aesthetic medicine, dermatologists or physicians specialising in plastic, reconstructive and/or aesthetic surgery. Before using the device, scan the QR code below to access training documentation on how to use the device, techniques and other useful information for the safe use of Algeness. Before use, mix the gel between the two syringes for at least ten (10) syringes for best consistency and results. Then, remove the syringe and empty connector and attach the supplied needle to the pre-filled syringe. Algeness® is a slowly absorbed filler and is totally biocompatible. It is indicated for the treatment of atrophic and hyperkeratotic skin changes and for the correction of wrinkles, skin folds, scars, or problems associated with traumatic injuries. The treatment must be performed by competent physicians trained in the use of injection techniques. Prior to injection, an anamnestic examination should be performed to identify possible patient/consumer-related factors, such as current and/or previous treatments or conditions that may affect the procedure.

Thorough cleansing and complete disinfection of the implant site should be carried out prior to injection. It is recommended to maintain proper asepsis of the treated area before, during and after implant insertion as well as to ensure a suitable (ambulatory) environment.
Place Algeness® under the site that is to be corrected at the level of the subdermis and at a variable depth depending on the agarose concentration. The amount to be injected into the subdermis and its depth is left to the judgement of the doctor. No more than 20 ml of Algeness should be applied at the same injection site during the session.
Algeness® should not be used in excess (overcorrection and/or overdose).
Correction can be carried out using the usual techniques: the detachment technique, the deep linear technique or the fan-shaped technique. Injection should be performed slowly for better placement of the product in the desired sites and less tissue trauma.

The product is extruded by applying continuous and constant pressure on the syringe plunger during needle withdrawal.
For optimal correction, always massage the treated area after implantation to ensure homogeneous distribution of the injected material.
It is advisable to apply cold to the treatment area to reduce any undesirable local reactions.
A monitoring period after administration is recommended to detect potential undesired side effects.
For proper maintenance of the result, remind the patient/consumer of the importance of follow-up several months after treatment.
The patient/consumer should also be informed that the treatment can be discontinued at any time at his/her request.
Inform the patient/consumer of the need not to apply cosmetics to the implant site for the next twelve hours and not to expose themselves to direct heat sources (e.g. exposure to the sun or UVA and UVB rays, use of hair dryers or hairdryers, reverberant heat from fireplaces, saunas, etc.) in the following days.

Do not exceed a maximum of 20 ml every 6 months.
For subsequent injections at the same site, wait at least 15 days after the previous session.
If properly used, the product has a useful life of about 6 months and complete reabsorption in about 12 months.

2.3 - Contraindications

It is contra-indicated in all cases other than those listed in the product's indications; therefore, it should not be injected superficially into the dermis or as a bolus.

Before injection make sure the patient/consumer has no particular hypersensitivity to any of the components of the product, otherwise do not use on such individuals.
As with all fillers, the product should not be used to correct particularly vascularised areas, as it may increase the risk of compression and occlusion of the vessels and related phenomenology.
Algeness should not be injected into individuals with acute or chronic skin conditions in or in the immediate vicinity of the areas to be corrected and, for prudential reasons, into individuals with a positive history of anaphylactic reactions or severe allergies, patients with severe organ or system diseases, including autoimmune diseases. The product is not intended for use in children, patients under 18 years of age, pregnant or lactating women.
It is recommended to avoid combined use with other substances such as crosslinked fillers in the same treatment area.
It must not be injected into blood vessels, as it may cause occlusion, local tissue necrosis or embolism.
The use of Algeness by users not included in the category indicated in the paragraph of indications, such as untrained, unqualified or unaccredited practitioners in the field of health or without a qualification in aesthetic medicine, dermatologists or doctors specialising outside the field of plastic, reconstructive and/or aesthetic surgery, is strictly prohibited.

3.0 DEVICE DESCRIPTION

3.1 - Description of the device

Algeness, is a device based on agarose, PPI water, phosphate buffer and, for VL and DF models, sodium hyaluronate.
Algeness, injected into the subdermal tissue, provides a viscoelastic supplement to the matrix. Agarose restores the lost tissue volume of both adipose tissue and connective stroma, ensuring biocompatibility with the extracellular matrix and harmony of natural shapes. Algeness is effective in cosmetic surgery aimed at correcting skin imperfections

related to the aetiology of tissue atrophy, i.e. wrinkles, folds and sunken scars, and can also be used for deep skin tissue fillers.
At the implant site, Algeness is reabsorbed in about 12 months.
It should be stored at room temperature, between 6 and 30°C, or, if necessary, in a refrigerator, avoiding freezing.
Algeness must not be used after the expiry date marked on the packaging.

3.2 – Previous generation or variants

The four Algeness models on the market are distinguished by the concentration of agarose, in particular the higher the agarose content, the more the device must be injected deep under the dermis. Below are the indications for use by model:

Algeness LD (low density - subdermal) is indicated for repairs and superficial subdermal corrections surface repairs and subdermal corrections of hypotrophy or tissue lesions such as in the perioral area.

Algeness HD (medium density - subdermal) is indicated for repairs and superficial subdermal corrections due to hypotrophy or tissue lesions in the perioral area.

Algeness VL (medium / high density - deep subdermal) is indicated in the volumetric restoration for all forms of deep tissue hypotrophy with severe or modest loss of tone of the deep ligaments such as in the suborbital areas and in the anterior mandibular area, include correcting nasolabial wrinkles.

Algeness DF (high density - deep subdermal) is indicated all forms of volumetric restorations for all forms of severe deep tissue hypotrophy with severe loss of volume and tone of the deep ligaments such as in the suborbital areas and in the anterior mandibular area, include correcting nasolabial wrinkles.

3.3 - Description of any accessories

The product is sold in a pre-filled syringe that connects via Luer connector to a second empty syringe to allow mixing of the gel before use. The double syringe comes with a wing to increase the contact surface area and a hypodermic needle to be used in connection with the pre-filled syringe for injection. Each syringe comes with an implant card that must be completed by the doctor, as per the instructions in the package insert, and given to the patient/consumer.

4.0 RISKS AND WARNINGS

4.1 - Residual risks & undesirable effects

The manufacturer has the expertise and know-how to conduct risk management according to the harmonised standard ISO 14971 and ISO/TR 24971: through this method, no unacceptable residual risks have been recorded following actions taken to mitigate those identified. Some of the residual risks are controlled by listing warnings and side effects in the package insert.

Despite this, implantation may pose risks of infection if the product is injected into anatomical sites where inflammatory or infectious processes are present, or without proper cleansing and disinfection of the area to be corrected. In patients with bleeding and/or coagulation disorders or during treatment with anticoagulants, the product must be used with caution, as the injection act may more frequently cause local bleeding or bruising.

Following implantation, slight to moderate oedematous reactions or reddening of the skin may rarely occur, and these resolve completely within a few days.

Although the application of Algeness® is not painful, the possibility of rare reports of transient pain from the injection act cannot be excluded, especially in particularly sensitive areas. The use of the resorbable, biocompatible aesthetic filler may entail some side effects. Common side effects and recommended treatments are listed below.
Treatment of common side effects

- Nodules: Nodules may appear within the first four weeks after injection and are single, well-confined and non-inflammatory. Prolonged massage or dispersal of the nodule through a cannula accelerates its biodegradation.
- Hardening: the slow and precise injection technique can prevent this effect. If it occurs, it is necessary to perform a gentle massage, and if necessary apply warm compresses. In some cases it is advisable to proceed with a broad-spectrum antibiotic treatment, for which medical advice should be sought.
- Inflammation: Apply cold compresses and use anti-inflammatory creams if necessary. The inflammation should subside within a few days.
- Immune response: Agarose gel is a pure polysaccharide and does not contain any proteins, cross-linking agents or chemicals; therefore, the immune reaction is

	extremely low but can be managed by a doctor's antihistamine treatment if necessary. - Swelling: any trauma, including injections, can cause temporary swelling. Applying cold and sleeping with the head slightly elevated can promote fluid drainage and reduce swelling. In some cases, gentle massage or the use of anti-inflammatory creams/gel is recommended. - Pain: Typically disappears immediately after the injection act, but in other cases can be relieved with painkillers such as paracetamol or ibuprofen. Avoid aspirin and other anticoagulants to reduce the risk of haematoma. - Haematoma: Bruising or haematoma formation is common. Apply cold compresses and use arnica-based creams to accelerate bruise resolution. Avoid sun exposure to affected areas. - Edema: Apply cold compresses and drink plenty of water to facilitate lymphatic drainage. Reduce salt intake to avoid further water retention. - Overdosage: As Algeness is a hydrocolloid, there is no possibility of an unexpected increase in volume. However, if it is certain that there is an overcorrection after injection, the filler can be dispersed with an injection of warm saline and massage in the initial period. A doctor must be consulted immediately if necessary and if adverse reactions and side effects occur. In addition to the common side effects, other less common effects may also occur, which include but are not limited to: - Capsule formation or capsular contractures, - Infection, - Superficial wounds, - Hyperpigmentation, - Syeroma, - Increased pressure within the compartment, - Granuloma. These side effects are less likely but should be monitored closely. If any of these symptoms or others occur, it is essential to consult a doctor immediately..
4.2 – Warnings and precautions	Before using the product, the patient/consumer must be provided with the instructions for use in order to be informed about the indications, professional use only, contraindications and possible side effects, including their treatment measures, that may occur with the implant. Strictly follow the recommended injection techniques to minimise the likelihood of occurrence of the indicated side effects. Maintain proper hygiene during treatment to prevent infection. If you do not perform a thorough technique and massage following injection, lumps may appear in the treated area. DISPOSABLE product. Sterile product. Must not be re-sterilised. The stamps on the inner packaging indicating the sterility of the product must be red, otherwise DO NOT use the product. In case of abnormal packaging, isolate non-compliant packaging and dispose of as special waste. Never use the product if not stored correctly or if subjected to freezing. Unused material remaining in the syringe should be discarded (disposed of) after treatment to avoid the risk of cross-infection from use on other patients. The physician and/or patient/consumer should report any serious incidents occurring with the device to the Ghimas manufacturer and to the competent authority of the Member State where the user and/or patient/consumer is established. FOR PROFESSIONAL USE ONLY. DO NOT USE the product after the expiration date printed on the package. Use the needle supplied or similar specification below.
4.3 – Other relevant aspects of safety	The medical device Algeness, since their first marketing date, have never been subject to any field safety corrective action (FSCA) or field safety notification (FSN).

5.0 CLINICAL EVALUATION and Post market clinical follow-up (PMCF)

(Summary of clinical evaluation in accordance with Annex XIV of Reg. 2017/745)

5.1 - Summary of clinical data from conducted investigations of the device before the CE-marking

A recent and important study, concluded by Dr Scuderi in 2019, summarised the effects after using the Algeness VL device. In particular, the study demonstrates the safety and performance of the device implanted in the affected site for the correction of nasolabial wrinkles in comparison with a hyaluronic acid (HA) filler, currently the most widely used and commercially available. It was also possible to record the judgments of the investigators on the handling and management of the product used, tolerability of the product, evaluation of the duration of the filler and opinions on patient satisfaction.

In this study, with a protocol authorised by the independent ethics committee (IEC), both products were used on each patient (68 total), thus excluding individual susceptibility.
In conclusion, the study demonstrated the following results:

- Algeness is completely absorbed in about 8 months.
- There are no differences in the safety aspects of the two fillers
- No serious or unexpected adverse effects were recorded

5.2 - Summary of clinical data from other sources

Clinical data from PMCF surveys and refereed scientific literature support the performance and safety of the device; in fact, the use of Algeness as a device for treating skin imperfections and restoring the natural structure of dermal tissue is safe and suitable for this purpose.
Clinical results from questionnaires collected, clinical investigations and scientific articles objectively and professionally demonstrate the safety and performance of Algeness.
These data, but above all the absence of specific product issues collected in the field, confirm the excellent tolerability and effectiveness of the device in non-surgical soft tissue correction, among other things, with the absence of persistent undesirable effects.
As there are no residual risks and/or performance or safety aspects to be investigated, there is no need to initiate further studies to determine the safety and performance of the device as there are no issues related to use, safety issues or performance aspects to be investigated.
The clinical results identified therefore concern the restoration of normal tissue morphology, its volumetries and symmetries, thus making the aged tissue look natural.
Dr. Scuderi's study focused on the safety of the device and on the aesthetic results, which, together with the data collected through surveys, show that all the imperfections treated have been considerably reduced with a clear reduction in the depth of the imperfection and in some cases almost completely eliminated. The overall condition of the cases is significantly improved, as per the indicated improvement index, and the performance on patients is confirmed.
The risks associated with the implantation of the device were found and confirmed to be minimal, as its integration with the host tissue occurs naturally and consistently with its nature, filling in the gaps and compensating for the lack of tissue volume.
No serious adverse reactions, previously unidentified undesirable effects or inflammatory reactions triggered by the immune system have emerged. Therefore, all identified risks were assessed in the risk analysis document, mitigated, and kept under control.

5.3 - Summary of the clinical performance and safety

The behaviour of the filler within the host tissue, with regard to safety and biocompatibility, has been carefully studied by some authors who, following the injection of filler with 1.5% agarose, concluded that, at a distance of six months, the filler was well adhered to the hypodermis, a physiological increase in collagen fibres was noted and the tissue was still well vascularised without any signs of granulomas or fibrosis.
The same check, carried out one year after the injection, allowed us to state that the filler had been completely absorbed and that at the level of the dermis-hypodermis there was a thickening of collagen. The connective tissue and its structure are similar to what emerged from the tissue biopsy prior to implantation, so there were no alterations.
The analysed data confirm the adequate performance and safety of the product:

- Natural and biodegradable: the product is not rejected following its injection because, being agarose-based, it is naturally accepted by the cells formed at the treatment site. This advantage is also confirmed by the few adverse reactions that have occurred in both literature research and customer reports.
- Restructuring: following treatment, the restorative effect is immediately noticeable and does not cause swelling in the following days because it is not a hydrophilic substance that attracts water molecules, unlike the more common hyaluronic acid fillers.
- Gradually reabsorbed: the natural composition of the gel allows its complete degradation in a longer time as the agarose is not directly attacked by an enzyme,

but is subjected to macrophage action and subsequently attacked by galactosinases with detachment of the molecules constituting the polymer.
- A homogeneous, soft gel consisting of a three-dimensional, rigid mesh network capable of holding molecules and organic liquids in dynamic equilibrium with its reabsorption, easy to extrude by light thumb pressure on the syringe plunger and through smaller gauge needles (27-30 Gauge).
- Little or no pain during implantation.
- Ideal implantation in the medium and deep dermis, with variable orientation of the flute beak, depending on the anatomical region treated and the characteristics of the imperfection.
- Post-implantation oedema contained, dose dependent, in rare cases with amplifications lasting 24-48 hours.
- Correction effectiveness lasts for about 6 months and complete reabsorption in about 12 months

In conclusion, all biocompatibility tests performed on the reference Algeness device were valid for the current EN ISO 10993 series of standards. The absence of acute and subacute/subchronic toxicity effects, irritation, sensitisation, genotoxic and reproductive potential, mutagenic potential and short- and long-term systemic toxicity effects after intramuscular implantation allows the biocompatibility of the Algeness devices to be confirmed.

5.4 - Ongoing or planned post-market clinical follow-up

In order to support the use of the product after many years on the market and to confirm what emerged from the preclinical studies and Dr Scuderi's clinical study regarding the safety of the device, post-marketing activities were initiated in which, from the questionnaires drawn up by professional users, information emerged that supports the safety and tolerability of the product because it immediately achieves the expected results and has therefore restored the morphology of the tissue, performing in line with the claims.
There were no signs of immune system activation and no adverse effects.
No risks and serious side effects emerged from the injection of the product, therefore, the device was safe with a risk profile associated with the treatment to the advantage of the applicability and use of Algeness as an aesthetic filler.

6.0 POSSIBLE THERAPEUTIC ALTERNATIVES

The Algeness device for aesthetic use is not involved in the treatment of a pre-existing pathology or trauma but is used on healthy consumers who wish to improve their appearance. For this reason, there are no therapeutic alternatives to be considered.

7.0 SUGGESTED PROFILE AND TRAINING FOR USERS

The device should only be used by professional, medical users who are familiar with and skilled in injection techniques. The injection must be performed in a medical practice that complies with health regulations. Therefore, it is recommended to maintain proper asepsis of the treated area before, during and after insertion of the implant as well as to ensure a suitable environment.

8.0 REFERENCE TO ANY HARMONISED STANDARDS AND CS APPLIED

The device is manufactured within a contamination-controlled clean room and is subsequently sterilised using Gamma rays; for these aspects, the product follows the common ISO standards concerning sterilisation processes, clean room validation and clinical evaluation and investigation. In particular, the reference standards are the following:

UNI CEI EN ISO 13485:2016+ A11:2021 "Medical devices - Quality management systems - Requirements for regulatory purposes" (acknowledges EN ISO 13485: 2016 + AC: 2018)
EN ISO 14971:2019 + A11:2021 Medical devices - Application of risk management to medical device
EN ISO 15223-1:2021 Medical devices - Symbols to be used in medical device labels, labeling and information to be provided - Part 1: General requirements
IS**O 10993-1:2021** Biological evaluation of medical devices Evaluation and testing within a risk management process
ISO 10993-2:2006 Biological evaluation of medical devices Part 2: Animal welfare requirements
ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
ISO 10993-6:2016 Biological evaluation of medical devices Part 6: Tests for local effects after implantation

ISO 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials
ISO 10993-16:2018 Biological evaluation of medical devices Part 16: Toxicokinetic study design for degradation products and leachables
ISO 10993-17:2009 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2009 Biological evaluation of medical devices Part 18: Chemical characterization of materials
ISO 10993-23: 2021 Biological evaluation of medical devices Part 23: Tests for irritation
ISO/TS 10993-19:2006 Biological evaluation of medical devices Part 19: Physico-chemical, morphological and topographical characterization of materials
ISO/TR 15499:2016 Biological evaluation of medical devices — Guidance on the conduct of biological evaluation within a risk management process
EN 62366:2008 Medical devices - Application of engineering of use characteristics to medical devices
UNI EN ISO 11137-1: 2020 Sterilization of healthcare products - Radiation - Part 1: Requirements for the development, validation and systematic control of the sterilization process for medical devices.
UNI EN ISO 11137-2:2015 Sterilization of healthcare products - Radiation - Part 2: Definition of the sterilizing dose
UNI EN ISO 11737-1:2018 + A1:2021 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
UNI EN ISO 11737-2:2021 Sterilization of medical devices - Microbiological methods - Part 2: Sterility tests performed during the definition, validation and maintenance of a sterilization proces
UNI EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
UNI EN ISO 11607-2:2020 Terminally Sterilized Medical Device Packaging - Part 2: Validation Requirements for Format, Seal and Assembly Processes
UNI EN ISO 14644-14:2016 Clean rooms and associated controlled environments - Part 14: Evaluation of the fitness for use of an equipment by determining the concentration of particles in the airport
UNI EN ISO 14644-2:2016 Cleanrooms and Associated Controlled Environments - Part 2: Monitoring to provide evidence of cleanroom performance in terms of air cleanliness in terms of particle concentration.

9.0 DATE AND SIGNATURE OF RESPONSIBLE FOR DRAFTING

Dott. Alberto Poletti –
RAQ e Responsible Person of MDR

10.0 REVISION HISTORY

SSCP Revision N°	Date issued	Change description	Revision validated by the Notified Body
00	31 May 2024	First issue for aesthetic use	☒**Yes_ language Italian and english** ☐**No** (only applicable for class IIa or some IIb implantable devices)

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Summary of safety and clinical performance (SSCP) for patients

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. IDENTIFICAZIONE DEL DISPOSITIVO MEDICO

Device trade name	**ALGENESS LD, ALGENESS HD, ALGENESS VL, ALGENESS DF**
Manufacturer	GHIMAS S.p.A. Via Domenico Cimarosa, 85, 40033 – Casalecchio di Reno, BO, Italy
Basic UDI-DI	ALGENESS LD: 803357637ALGENESS10YU ALGENESS HD: 803357637ALGENESS15Z6 ALGENESS VL: 803357637ALGENESS25Z9 ALGENESS DF: 803357637ALGENESS35ZC
Year of the first certificate (CE)	2004

2. INTENDED USE

Intended purpose	In the aesthetic field, Algeness is a resorbable filler indicated for the correction of skin imperfections caused by wrinkles, folds or sunken scars. In particular, the use of Algeness VL and DF is also specifically indicated for the correction of nasolabial wrinkles..
Indications	Algeness may only be used by physicians qualified in aesthetic medicine, dermatologists or physicians specialising in plastic, reconstructive and/or aesthetic surgery. Before using the device, scan the QR code below to access training documentation on how to use the device, techniques and other useful information for safe use of Algeness. Prior to use, mix the gel between the two syringes for at least ten (10) for best consistency and results. Afterwards, remove the syringe and empty connector and connect the supplied needle to the pre-filled syringe. Algeness® is a slowly absorbed filler and is totally biocompatible. It is indicated for the treatment of atrophic and hyperkeratotic skin changes and for the correction of wrinkles, skin folds, scars, or for problems associated with traumatic injuries. The treatment must be performed by competent physicians trained in the use of injection techniques. Prior to the injection, an anamnestic examination should be performed to identify possible patient/consumer-related factors, such as current and/or previous treatments or conditions that may affect the procedure. Before injection, thorough cleansing and complete disinfection of the implant site must be carried out. It is recommended to maintain proper asepsis of the treated area before, during and after implant insertion as well as to ensure a suitable (ambulatory) environment. Place Algeness® under the site you want to correct at the level of the subdermis and at a variable depth depending on the agarose concentration. The amount to be injected into the subdermis and its depth is left to the judgement of the doctor. The amount of Algeness applied at the same injection site during the session should not exceed 20 ml. Algeness® should not be used in excess (overcorrection and/or overdose). Correction can be carried out using the usual techniques: the décolletage technique, the deep linear technique or the fan-shaped technique. The injection should be performed slowly for better placement of the product in the desired sites and less tissue trauma. The product is extruded by applying continuous and constant pressure on the syringe plunger during needle extraction. For optimal correction, always massage the treated area after implantation to ensure homogeneous distribution of the injected material.

	It is advisable to apply cold to the treatment area to reduce any unwanted local reactions. A monitoring period after administration is recommended to detect potential unwanted side effects. For proper maintenance of the result, remind the patient/consumer of the importance of follow-up several months after treatment. The patient/consumer should also be informed that the treatment can be discontinued at any time at his/her request. Inform the patient/consumer of the need not to apply cosmetics to the implant site for the next twelve hours and not to expose themselves to direct heat sources (e.g. exposure to the sun or UVA and UVB rays, use of hair dryers or hairdryers, reverberant heat from fireplaces, saunas, etc.) in the following days. Do not exceed a maximum of 20 ml every 6 months. For subsequent injections at the same site, wait at least 15 days after the previous session. The product, when properly used, has a useful life of about 6 months and complete reabsorption in about 12 months.
Contraindications	It is contraindicated in all cases other than those listed in the product's indications, so it should not be injected superficially into the dermis or as a bolus. Before injection make sure the patient/consumer has no particular hypersensitivity to one of the components of the product, otherwise do not use on such individuals. As with all fillers, the product should not be used to correct particularly vascularised areas, as it may increase the risk of compression and occlusion of the vessels and related phenomenology. Algeness should not be injected into individuals with acute or chronic skin conditions in or in the immediate vicinity of the areas to be corrected and, for prudential reasons, into individuals with a positive history of anaphylactic reactions or severe allergies, patients with severe organ or system diseases, including autoimmune diseases. The product is not intended for use in persons under 18 years of age, pregnant or lactating women. It is recommended to avoid combined use with other substances such as crosslinked fillers in the same treatment area. It should not be injected into blood vessels, as it may cause occlusion, local tissue necrosis or embolism. It is strictly forbidden to use Algeness by users not included in the category indicated in the paragraph of indications, such as operators not trained, qualified or accredited in the medical field or without a qualification in aesthetic medicine, dermatologists or doctors specialising outside the field of plastic, reconstructive and/or aesthetic surgery.
Pazienti target	The target population includes patients/consumers with skin imperfections, dermal atrophy and connective tissue deficits and who are not included in the populations described in the contraindications section.

3. DEVICE DESCRIPTION

Description of the device	Algeness, is a device based on agarose, PPI water, phosphate buffer and, for VL and DF models, sodium hyaluronate. Algeness, injected into the subdermal tissue, provides a viscoelastic supplement to the matrix. Agarose restores the lost tissue volume of both adipose tissue and connective stroma, ensuring biocompatibility with the extracellular matrix and harmony of natural shapes. Algeness is effective in cosmetic surgery aimed at correcting skin imperfections related to the aetiology of tissue atrophy, i.e. wrinkles, folds and sunken scars, and can also be used for deep skin tissue fillers. At the implant site, Algeness is reabsorbed in about 12 months.
Description of any accessories	The product is sold in a pre-filled syringe that connects via Luer connector to a second empty syringe to allow mixing of the gel before use. The double syringe comes with a wing to increase the contact surface area and a hypodermic needle to be used in connection with the pre-filled syringe for injection. Each syringe comes with an implant card that must be completed by the doctor, as per the instructions in the package insert, and given to the patient/consumer.

4. RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Potential risk management

As a manufacturer of devices, which it markets under its own name, GHIMAS SPA maintains an active process to identify hazards that can be associated with its own devices, to estimate and assess the resulting risks, to control the risks themselves and to monitor the effectiveness of this process.
Data are collected through a post-marketing surveillance plan, which Ghimas updates annually, through which information from various sources, such as databases, scientific articles, reports and complaints, is summarised, analysed and discussed to identify possible new risks.

Residual risks & undesirable effects

Ghimas has the skills and know-how to conduct risk management according to the harmonised standard recognised worldwide: through this method, no unacceptable residual risks have been recorded following actions taken to mitigate those identified.
Some of the residual risks are controlled by listing warnings and side effects in the package insert.
Despite this, implantation may pose risks of infection if the product is injected into anatomical sites where inflammatory or infectious processes are present, or without proper cleansing and disinfection of the area to be corrected. In patients with bleeding and/or coagulation disorders or during treatment with anticoagulants, the product must be used with caution, as the injection act may more frequently cause local bleeding or bruising.
Following implantation, slight to moderate oedematous reactions or reddening of the skin may rarely occur, and these resolve completely within a few days.
Although the application of Algeness® is not painful, the possibility of rare reports of transient pain from the injection act cannot be excluded, especially in particularly sensitive areas. The use of the resorbable, biocompatible aesthetic filler may entail some side effects. Common side effects and recommended treatments are listed below.
Treatment common side effects

- Nodules: Nodules may appear within the first four weeks after injection and are single, well-confined and non-inflammatory. Prolonged massage or dispersal of the nodule through a cannula accelerates its biodegradation.
- Hardening: the slow and precise injection technique can prevent this effect. If it does occur, gentle massage is required, and warm compresses should be applied. In some cases it is advisable to proceed with a broad-spectrum antibiotic treatment, for which a medical consultation should be sought.
- Inflammation: Apply cold compresses and use anti-inflammatory creams if necessary. The inflammation should subside within a few days.
- Immune response: agarose gel is a pure polysaccharide and does not contain any proteins, cross-linking agents or chemicals; therefore, the immunological reaction is extremely low, but can be managed if necessary by means of a doctor-designed antihistamine treatment.
- Swelling: any trauma, including injections, can cause temporary swelling. Applying cold and sleeping with the head slightly elevated can promote fluid drainage and reduce swelling. In some cases, gentle massage or the use of anti-inflammatory creams/gel is recommended.
- Pain: Typically it disappears immediately after the injection act, but in other cases it can be relieved with painkillers such as paracetamol or ibuprofen. Avoid aspirin and other anticoagulants to reduce the risk of bruising.
- Haematoma: Bruising or haematoma formation is common. Apply cold compresses and use arnica-based creams to accelerate bruise resolution. Avoid sun exposure on affected areas.
- Edema: Apply cold compresses and drink plenty of water to facilitate lymphatic drainage. Reduce salt intake to avoid further water retention.
- Overdose: As Algeness is a hydrocolloid, there is no possibility of an unexpected increase in volume. However, if it is certain that there is an overcorrection after injection, the filler can be dispersed with an injection of warm saline and massage in the initial period.

The doctor must be consulted immediately if necessary and if adverse reactions and side effects occur.
In addition to the common side effects, other less common effects may also occur, including but not limited to:

- Capsule formation or capsular contractures,
- Infection,
- Superficial wound,
- Hyperpigmentation,
- Seroma,

- Increased pressure inside the compartment,
- Granuloma.

These side effects are less likely but should be monitored closely. If any of these symptoms or others occur, it is essential to consult a doctor immediately.

Warnings

Before using the product, the patient/consumer must be provided with the enclosed, completed instructions and must be informed about the indications, contraindications and possible side effects that may occur with use. In addition, the patient/consumer must be informed that Algeness must be injected by physicians in accordance with the above qualification.
Strictly follow the recommended injection techniques to minimise the likelihood of occurrence of the indicated side effects.
Maintain proper hygiene during treatment to prevent infection.
If careful technique and massage is not performed following injection, lumps may appear in the treated area.
DISPOSABLE product. STERILE product. Must not be re-sterilised.
The stamps on the inner packaging indicating the sterility of the product must be red, otherwise DO NOT use the product. In case of abnormal packaging, isolate non-compliant packaging and dispose of as special waste. Never use the product if not stored correctly or if subjected to freezing.
Unused material remaining in the syringe should be discarded (disposed of) after treatment to avoid the risk of cross-infection from use on other patients.
The physician and/or patient/consumer should report any serious incidents occurring with the device to the Ghimas manufacturer and to the competent authority of the Member State where the user and/or patient/consumer is established.
FOR PROFESSIONAL USE ONLY.
DO NOT USE the product after the expiration date printed on the package.
Use the needle supplied or similar specification below.

Precautions and indications

As with all percutaneous procedures, implantation may involve risks of infection if the product is injected into anatomical sites where inflammatory or infectious processes are present, or without proper cleansing and disinfection of the area to be corrected.
In patients with bleeding and/or coagulation disorders or during treatment with anticoagulants, the product must be used with caution, as the injection act may more frequently cause local bleeding or bruising.

Algeness is only indicated for users such as doctors qualified in aesthetic medicine, dermatologists or doctors specialising in plastic, reconstructive and/or aesthetic surgery.
The treatment must be performed by competent physicians trained in the use of injection techniques.

Algeness® is a slowly absorbed filler and is totally biocompatible. It is indicated for the treatment of atrophic and hyperkeratotic skin changes and for the correction of wrinkles, skin folds, scars, or for problems associated with traumatic injuries.
The treatment must be performed by competent physicians trained in the use of injection techniques.
A monitoring period after administration is recommended to detect potential unwanted side effects.
For proper maintenance of the result, remind the patient/consumer of the importance of follow-up several months after treatment.
The patient/consumer should also be informed that the treatment can be discontinued at any time at his/her request.
Inform the patient/consumer of the need not to apply cosmetics to the implant site for the next twelve hours and not to expose themselves to direct heat sources (e.g. exposure to the sun or UVA and UVB rays, use of hair dryers or hairdryers, reverberant heat from fireplaces, saunas, etc.) in the following days.
Do not exceed a maximum of 20 ml every 6 months.
For subsequent injections at the same site, wait at least 15 days after the previous session.
The product, when properly used, has a useful life of about 6 months and complete reabsorption in about 12 months.

5. CLINICAL EVALUATION and Post market clinical follow-up (PMCF)

Clinical background

The field of fillers, substances for injective use used to restore and correct damage resulting from dermal atrophy but also for corrective treatment aimed at restoring normal morphology, rehydrating and supporting tissues, is constantly evolving and evolving.

One of the most interesting features of this filler (compared to other resorbables) seems to have been its duration, which was certainly longer than 6 months even in the last case history review published in 2018 and also from what emerged in the 2019 multicentre study. It is likely, in fact, that the longer duration is attributable to the different resorption modes. Agarose, in comparison with collagen- or hyaluronic acid-based fillers, is not directly attacked by the corresponding enzyme (the human body does not possess agarase) but degraded after macrophage attack.

On the basis of observations and clinical experience after years of using fillers from the ALGENESS line, in the first published works some authors (in 2005, 2006 and 2008) reaffirmed the characteristic properties of agarose gel.

All biocompatibility tests carried out on reference Algeness confirm what has been described in the published articles. The absence of acute and subacute/subchronic toxicity effects, irritation, sensitisation, genotoxic and reproductive potential, mutagenic potential and short- and long-term systemic toxicity effects after intramuscular implantation allows the biocompatibility of Algeness to be confirmed.

Clinical evidence for the CE-marking

A recent and important study, concluded in 2019, summarised the effects after use of the Algeness VL device. In particular, the study, together with data from case reports, demonstrates the safety and performance of the device implanted in the affected site for the correction of nasolabial wrinkles in comparison with a hyaluronic acid (HA) filler, currently the most widely used and commercially available. It was also possible to record the judgments of the investigators on the handling and management of the product used, tolerability of the product, evaluate the durability of the fillers and obtain opinions on patient satisfaction.
In this study, with a protocol authorised by the Independent Ethics Committee (IEC), both products were used on each patient (68 total), Algeness was compared with a hyaluronic acid product, thus excluding individual susceptibility.
In conclusion, the study demonstrated the following results:

- Algeness is completely absorbed in about 8 months.
- There are no inherent differences in safety aspects between the two fillers
- No serious or unexpected adverse effects were recorded

Summary of safety

The behaviour of the filler within the host tissue, with regard to safety and biocompatibility, has been carefully studied by some authors who, following the injection of filler with 1.5% agarose, concluded that, at a distance of six months, the filler is well incorporated into the hypodermis, an increase in collagen fibres has been noted and the tissue is still well vascularised without any signs of granulomas or fibrosis.
The same check, carried out one year after the injection, allowed us to state that the filler had been completely absorbed and that at the level of the dermis-hypodermis there was a thickening of collagen. The connective tissue and its structure are similar to what emerged from the tissue biopsy prior to implantation, so there have been no alterations.

The absence of acute and subacute/subchronic toxicity effects, irritation, sensitisation, genotoxic and reproductive potential, mutagenic potential, and short- and long-term systemic toxicity effects after intramuscular implantation allows the biocompatibility of Algeness devices to be confirmed.

In order to support the use of the product after many years on the market and to confirm what emerged from the preclinical studies and Dr Scuderi's clinical study, post-marketing activities were launched in which, from the questionnaires drawn up by professional users, information emerged supporting the product's safety and tolerability because it immediately achieves the expected results and therefore compensates for the lack of tissue volume without the activation of the immune system and therefore without adverse effects. No serious risks and side effects emerged from the injection of the

product, therefore, the device was found to be safe with a risk profile associated with the treatment benefiting the applicability and use of Algeness.

6. ALTERNATIVE POSSIBLE THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended that you first contact your medical professional who can assess your individual situation and help you choose the best product to use as an aesthetic filler.
The Algeness device for aesthetic use is not involved in the treatment of a pre-existing pathology or trauma but is used on healthy consumers who wish to improve their appearance. For this reason, there are no therapeutic alternatives to be considered.

7. SUGGESTED PROFILE AND TRAINING FOR USERS

Algeness is only indicated for users such as doctors qualified in aesthetic medicine, dermatologists or doctors specialising in plastic, reconstructive and/or aesthetic surgery
The use of Algeness by users who are not included in the category indicated in the paragraph of indications, such as practitioners who are not trained, qualified or accredited in the field of health care or without a qualification in aesthetic medicine, dermatologists or physicians specialising outside the field of plastic, reconstructive and/or aesthetic surgery is strictly prohibited.
The device should only be used by professional, medical users who are familiar with and skilled in injection techniques. The injection must be performed in a medical practice that complies with health regulations. Therefore, it is recommended to ensure proper asepsis of the treated area before, during and after insertion of the implant as well as a suitable environment.

8. DATE AND SIGNATURE OF RESPONSIBLE FOR DRAFTING

Dott. Alberto Poletti –
RAQ e Responsible Person of MDR

9. REVISION HISTORY

SSCP Revision N°	Date issued	Change description	Revision validated by the Notified Body
00	31 May 2024	First issue for aesthetic use	☒**Yes: language Italian and english** ☐**No** (only applicable for class IIa or some IIb implantable devices)