ADAGA

ADAGA LIFECHIT CHITOSAN BASED HAEMOSTATIC GRANULES SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

In accordance with

Medical Device Regulation 2017/745 (MDR)

And

MDCG 2019-9

Revisions page

Language: English

Rev	Date	Explanation (Description of Change)	Validated by the Notified Body
01	18.03.2026	• Initial preparation	

Contents

Revisions page 2
List of abbreviation / glossary 5
1. Device identification and general information 6
1.1. Information about the device 6
1.2. Manufacturer's name and address 6
1.3. Manufacturer's Single registration Number 6
1.4. Basic UDI-DI 6
1.5. Year when the first certificate (CE) was issued covering the device 6
2. Intended purpose of the device 7
2.1. What is the device used for and who is it for? 7
2.2. When should the device NOT be used? (Contraindications) 7
3. Device description 8
3.1. What is the device and what is it made of? 8
3.2. How does it work to stop bleeding? 8
3.3. How is it supplied? 8
4. Risks and warnings 8
4.1. How potential risks have been controlled or managed? 9
4.2. Warnings and precautions 9
4.3. Summary of any field safety corrective action (recalls) 9
5. Summary of clinical evaluation and post-market clinical follow-up 10
5.1. Clinical background of the device 11
5.2. The clinical evidence for the CE-marking (Does the device work?) 11
5.3. Safety 11
5.4. Post-market clinical follow-up (What happens next?) 11
6. Possible diagnostic or therapeutic alternatives 11
6.1. What are the alternative treatments? 12
6.2. How does this device compare? 12

7. Suggested training for users 12

7.1. Who can use this device? 12

7.2. What training is required? 13

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 the Instructions For Use to provide information on the safe use of the device

The English version of this SSCP document (TF.01-12.05) has been validated by the notified body

List of abbreviation / glossary

Basic UDI-DI	Basic Unique device identification device identifier
CAPA	Corrective and preventive action
FSCA	Field safety corrective action
FSN	Field safety notice
PMCF	Post Market Clinical Follow-up
PMS	Post Market Surveillance
SSCP	Summary of Safety and Clinical Performance
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

1. Device identification and general information

1.1. Information about the device

PRODUCT NAME	Adaga LifeChit Chitosan Based Haemostatic Granules
BRANDS	Adaga LifeChit

1.2. Manufacturer's name and address

MANUFACTURER	ADAGA SAĞLIK KİMYA SANAYİ A.Ş.
Address (Central Office) Address (Manufacturing and Storage)	: Şerifali Mah. Kule Sok. Bulut Apt. No:13/10 ÜMRANİYE/ İSTANBUL : Altıayak Mh. 8525 Sok. No: 22/E Kepez/ANTALYA

1.3. Manufacturer's Single registration Number

SRN NUMBER	TR-MF-000046179

1.4. Basic UDI-DI

Basic UDI-DI	Adaga LifeChit Chitosan Based Haemostatic Granules	868196749AZ0000MZ

1.5. Year when the first certificate (CE) was issued covering the device

The product will be certified for the first time within the scope of (EU) 2017/745; the initially certification process is continuing.

2. Intended purpose of the device

2.1. What is the device used for and who is it for?

Adaga LifeChit is a special powder (granules) used to quickly control and stop bleeding on the outside of the body. It is intended to be used for:

- Emergency first-Aid: To temporarily stop severe, life-threatening bleeding caused by accidents, such as traffic injuries, falls, stab wounds, or severe cuts, before reaching a hospital.
- Dental Procedures: To stop bleeding in the mouth during minor oral surgeries, such as tooth extractions or gum surgery.

It is intended for use on adult and pediatric patients who are experiencing severe bleeding.

2.2. When should the device NOT be used? (Contraindications)

- It must not be used during internal surgeries (except for dental/oral surgery in the mouth).
- It must not be put into the eyes.
- It must not be used on wounds where you cannot apply direct, firm pressure with your hand

3. Device description

3.1. What is the device and what is it made of?

Adaga LifeChit is a sterile powder (granules) that is poured directly onto a bleeding wound. The main ingredient in the device is chitosan, which is a natural, highly purified substance extracted from the shells of shrimp.

3.2. How does it work to stop bleeding?

When the granules are poured into the wound and you apply firm, direct pressure with your hands, the powder quickly absorbs the blood and fluids. As it mixes with the blood, the chitosan links together with your red blood cells to create a strong, gel-like seal (or plug) that completely covers the bleeding area. This physical plug stops the bleeding very quickly, and works independently of your body's normal blood-clotting process.

3.3. How is it supplied?

The granules are provided as a single-use product inside a sterile aluminium pouch. To accommodate different sizes of wounds and severities of bleeding, it is available in three different packet sizes: 2 grams, 5 grams, and 15 grams.

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.

4.1. How potential risks have been controlled or managed?

The manufacturer controls risks by carefully purifying the shrimp shells during manufacturing, heavily sterilizing the final product in its packaging to prevent infections, and providing clear instructions to ensure the powder is used correctly. The instructions also strictly guide medical staff to thoroughly wash the powder out of the wound once the bleeding has stopped and before the wound is closed.

- Remaining risks and undesirable effects Although the device is safe and effective, some side effects and risks may still occur. Based on clinical data, these are rare:
- Allergic reactions: A reaction may occur, especially if you have a known allergy to shellfish (like shrimp or crabs).
- Wound reactions: You may experience redness, swelling, heat (inflammation), or a localized infection at the wound site.
- Foreign body reactions: Small lumps (granulomas) may form under the skin if the powder is not completely washed out of the wound before it heals.
- Rebleeding: The bleeding may start again at the treated site.
- Fluid collection: Blood or fluid may collect under the skin, causing a bump (hematoma or seroma).
- Blood clots: There is a very rare risk of blood clots forming and moving into the bloodstream.
- Pressure injuries: If a large amount of the powder swells inside a closed space in the body, it could press against nerves or blood vessels.

4.2. Warnings and precautions

- For external use only: Do not use inside the body during surgeries (except for dental/oral surgeries in the mouth).
- Eye contact: Do not put the powder in your eyes. If it accidentally gets in your eyes, flush them with water for five minutes.
- Ingestion and inhalation: Do not eat or swallow the powder. If you swallow it, drink plenty of water to avoid discomfort. Avoid breathing in the powder.
- Shellfish allergy: Because the device contains chitosan made from shellfish, it must be used with caution if you are sensitive or allergic to shellfish products.
- Special populations: The safety of this device has not been fully proven in children, pregnant women, or breastfeeding women. A doctor must decide if the life-saving benefits outweigh the risks before using it on these patients.
- Do not use if damaged. Inspect the packet carefully. Do not use the powder if the aluminium pouch is damaged or open, as it may no longer be sterile and could cause an infection.
- Use the device only as instructed in this IFU.
- This device is intended for single use only.
- Do not re-use or attempt to re-sterilize the powder under any circumstances.

4.3. Summary of any field safety corrective action (recalls)

There have been no safety recalls or field safety corrective actions for this device because it is a newly certified product

5. Summary of clinical evaluation and post-market clinical follow-up

5.1. Clinical background of the device

Powders made from chitosan (shrimp shells) have a proven track record and have been used successfully for many years in emergency, trauma, and military medicine to stop severe bleeding. While the active ingredient has a long history of safety and performance, Adaga LifeChit itself is a new medical device that is currently undergoing its first European certification.

5.2. The clinical evidence for the CE-marking (Does the device work?)

To prove that the device safely stops bleeding, the manufacturer conducted a clinical study on 40 adult patients who had a tooth pulled (dental extraction).

- Rapid bleeding control: The study showed that the powder was highly effective. For all patients (100%), the bleeding was completely stopped within 10 minutes. On average, it took less than 2 minutes (about 117 seconds) to stop the active bleeding.
- No re-bleeding: None of the patients experienced any re-bleeding in the 24 hours after the treatment.

In addition to this study, the manufacturer reviewed 7 published medical studies involving similar chitosan-based products. These studies consistently confirmed that the powder rapidly controls severe bleeding and significantly reduces blood loss compared to using standard cotton gauze.

5.3. Safety

The clinical study demonstrated that the device is very safe for patients. Out of the 40 patients treated, there were zero (0) severe side effects or injuries related to the device. Only one patient experienced mild facial swelling, but the doctor determined it was unlikely to have been caused by the powder.

5.4. Post-market clinical follow-up (What happens next?)

Because Adaga LifeChit is a newly certified device, the manufacturer will continuously monitor how well and safely it works in the real world. They will do this by:

- Surveys: Collecting information and questionnaires from medical professionals and patients who use the device to monitor its performance and watch for any delayed side effects.
- Literature Review: Reviewing newly published medical and scientific literature every year to ensure the device remains safe according to the latest medical standards

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

6.1. What are the alternative treatments?

There are several other ways to manage and stop severe bleeding.

- Standard first aid: The most common alternative is applying firm, direct pressure to the wound using standard cotton gauze, bandages, or a clean cloth. For dental procedures, a dentist may use stitches (sutures) to close the gums.
- Hospital treatments: In a hospital or clinic setting, doctors can use special heat or energy tools to seal bleeding blood vessels.
- Other bleeding control products: There are also other medical sponges, powders, and gels designed to stop bleeding. These are often made from plant materials, animal collagen, or human blood proteins.

6.2. How does this device compare?

While standard direct pressure and gauze are the usual first-choice treatments, they may not be enough to stop very severe, life-threatening bleeding outside of a hospital. Other medical powders or sponges can be highly effective, but they might require special preparation or carry risks of severe allergic reactions or disease transmission. Adaga LifeChit is ready to use immediately and avoids the risks associated with human or animal-derived blood products. It provides a safe option to quickly control bleeding, provided the patient is not allergic to shellfish

7. Suggested training for users

7.1. Who can use this device?

Adaga LifeChit can be used by lay persons (everyday people without formal medical training) to self-administer emergency first aid. It is also used by trained emergency responders (like paramedics) and medical professionals (such as dentists or oral surgeons).

7.2. What training is required?

You do not need any special, device-specific medical training to use this powder for emergency bleeding. However, you should possess basic first aid knowledge.

Most importantly, before using the device, you must carefully read and fully understand the printed Instructions for Use (IFU) provided in the packaging to ensure you apply it safely and correctly. No additional or ongoing update training is required.