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)	Validation by the Notified Body
00	10.08.2023	Initial preparation	
01	18.03.2026	The report was revised, based on the findings from BSI's auditor in accordance with the requirements of MDCG 2019-9 Rev.1. Several corrections have been made; • Approval of the report has been removed as required of the validation by the Notified body, acc. to requirements of MDR and MDCG 2019-9 Rev.1 • Intended purpose, indications, contraindications and other relevant information about the device were revised aligning with the information on IFU. • Information about animal studies and studies belonging to the equivalent devices and other non-relevant information from literature have been removed. • Clinical data of the device has been summarized. • Ongoing clinical studies in accordance with the PMCF plan has been revised.	

Contents

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 Adaga LifeChit Chitosan Based Haemostatic Granules.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the Adaga LifeChit Chitosan Based Haemostatic Granules, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

The English version of this SSCP document (TF.01-12.04) 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)	: Şerifali Mah. Kule Sok. Bulut Apt. No:13/10 ÜMRANİYE/ İSTANBUL
Address (Manufacturing and Storage)	: 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. Medical Device nomenclature description, EMDN code

- Category: Special Dressing
- Code: M040501
- Description: POLYSACCHARIDE HAEMOSTATIC DRESSINGS

1.6. Class of device

DEVICE NAME: Adaga LifeChit Chitosan Based Haemostatic Granules		
BRAND NAME: Adaga LifeChit		
DEVICE GROUP WHICH THE DEVICE BELONGS, RISK CLASS	Relevant regualtion	(EU) 2017/745 for medical device
	Generic designation	Haemostatic dressings
	Classification	Class III
	Rule according to the 2017/745	Rule 18 (and Rule 4)
	Rationale for classification	According to MDR Annex VIII, Chapter II (Implementing Rules), Article 3.5, if several rules apply to the same

		device, the strictest rule resulting in the higher classification shall apply. While Rule 4 (Indent 4) applies and classifies the device as Class IIa for its contact with injured mucous membranes and minor skin injuries, the device utilizes animal tissue derivatives (shrimp shells). Therefore, Rule 18 applies, and the device is ultimately classified as Class III.

1.7. 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.

1.8. Authorized representative if applicable, name and the SRN

EC-REP:	N/A

1.9. Notified Body

Name	BSI Group The Netherlands B.V.
Address	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
Web Address	www.bsigroup.com
Notified Body Number	2797

2. Intended purpose, indication of the device

2.1. Intended purpose

Adaga LifeChit is a topical chitosan-based haemostatic agent intended to control and stop localized external bleeding.

2.2. Indications and target population

Adaga LifeChit is a topical chitosan-based haemostatic agent intended to control and stop localized external bleeding.

Adaga Lifechit can be used on the patients undergoing dental or minor oral surgical procedures who experience localized minor to moderate external bleeding

2.3. Contraindications

The device is not intended for surgical use, except dental/oral surgery. Do not use in wound unamenable to pressure. Adaga LifeChit should not be used in the eyes.

3. Device description

3.1. Description of the device

Adaga LifeChit is a very effective haemostat granule optimised to stop bleeding fast. It is made of a proprietary composition which contains chitosan. Chitosan is a natural polymer extracted from shrimp shells and highly purified. It is applied directly to the source of bleeding in a topical wound and pressure applied until haemostasis is achieved. It achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, it quickly forms a strong seal that completely covers the wound.

Adaga LifeChit hemostats have been found to be non-antigenic, non-pyrogenic and meet all requirements for chitosan specified at the European Pharmacopoeia (EP).

For different needs for hemostasis and severity of the bleeding Adaga LifeChit have been presented three different packaging form (2 g, 5 g, and 15 g).

Adaga LifeChit is available in sterile form in a aluminium pouch.

The product is obtained as a result of demineralization, deproteinization, deacetylation and various chemical processes from shrimp shells

3.2. Previous generations

There are no previous generation of the device produced.

3.3. Accessories

Device has no accessory.

3.4. Description of other devices used in combination

There is no device could be used in combination with Adaga LifeChit Chitosan Based Haemostatic Granules.

3.5. Risks and warnings

Risks related to use of Adaga LifeChit Chitosan Based Haemostatic Granules;

- Foreign body reaction
- Inflammatory reaction
- Infection
- Rebleeding at the treated site (with or without removal of the device after achievement of haemostasis)
- Hematoma/ seroma
- Thromboembolic hazards (blood clots)
- Compression-related problems (e.g. Stenosis, nerve damage, or sequalae related to decreased blood flow)

3.6. Potential adverse reactions

PMCF study, user surveys for both professional users and lay persons are planned in order to monitor potential adverse effects and assess the clinical performance and safety of the device after putting into the market, as indicated in TF.01-12.02 Post market clinical follow-up plan.

Celox Gauze, HemCon ChitoGauze, and other chitosan-based dressings contain much larger particles of a bioabsorbable chitosan that stick together when they get wet. Chitosan gauze manual application methods are identical to Combat Gauze but very different from WoundStat clay granules (smectite clay minerals applied as granules). Chitosan produces a localized hemostatic effect only over the damaged blood vessels. Multiple combat casualties had Celox Gauze successfully applied, and it stopped bleeding to all wounds caused by IED blast fragments and GSWs to the lower extremities, pelvic region, neck, ear, and nose without complications. Consequently, there is low risk of complication and embolic vessel migration with chitosan-based dressings.

The safety of chitosan has been extensively addressed but not definitively researched for the potential of chitosan particles resulting in emboli and particle migration into critical end organs. However, it is the consensus of the authors that the risk is judged to be very low based on the following facts:

- The cumulative experience from many decades of chitosan research in science and medicine.
- The tissue adhesion (non-procoagulant) mechanism of action exterior to the damaged artery.
- The biodegradation and bio-absorption properties.
- The knowledge gained from multiple preclinical (normal and coagulopathic) animal studies.
- Clinical case series of chitosan-based agents (granular) and dressings (gauze) with external application by numerous NATO combat medical personnel from the battlefield to obstetric use to control severe coagulopathic vaginal postpartum haemorrhage as well as surgical (off-label internal) application in the operating room. There have been no complications reported for long-term application of Celox Gauze in both external (48 hours) and internal (liver laceration) application (<14 days internal).

3.7. Residual risks and undesirable effects

In accordance with the clinical evaluation and risk management data, and aligned with the Instructions for Use (IFU), the expected undesirable side-effects and residual risks associated with the use of Adaga LifeChit Chitosan Based Haemostatic Granules include:

- Foreign body reaction (e.g., granuloma formation if particles remain in the wound bed)
- Inflammatory reaction
- Localized infection
- Rebleeding at the treated site (with or without removal of the device after achievement of haemostasis)
- Hematoma or seroma
- Thromboembolic hazards (e.g., blood clots or emboli entering the systemic circulation)
- Compression-related problems (e.g., stenosis, nerve damage, or sequelae related to decreased blood flow caused by product swelling in closed spaces)
- Hypersensitivity or allergic reaction in patients with known shellfish sensitivity

In the pre-market clinical investigation (Protocol: ALP-2021-HM-01-2021/02000) evaluating the haemostatic efficacy and safety of Adaga LifeChit in 40 patients undergoing dental extraction, the device was well-tolerated with a 0% incidence of serious adverse events. There were 0 device-related adverse events reported. A single mild adverse

event (1 case of facial edema) was recorded approximately 13 hours post-extraction; however, the clinical investigator judged its relationship to the medical device as "unlikely" and it resolved fully without action.

Furthermore, based on the systematic literature review and post-market vigilance data of equivalent chitosan-based haemostats, the real-world occurrence of these severe side-effects is highly rare.

The overall residual risks and undesirable side-effects are deemed acceptable when weighed against the life-saving clinical benefits of achieving rapid haemostasis and preventing exsanguination in emergency situations

3.8. 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.

3.9. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

As the product will be certified for the first time, neither Corrective and Preventive Actions (CAPA) nor Field Safety Corrective Actions (FSCA) have been performed

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

A well-structured survey study will be planned to collect evaluation data after the user's use of the product. The results of their surveys will be collected from users will be used to analyze the clinical safety and performance data of the device.

4.1. Summary of the clinical data related to equivalent device, if applicable

Not Applicable.

Conformity of the Adaga LifeChit device was not assessed and endorsed by the Notified Body on the basis of clinical equivalence.

As a Class III medical device, the clinical evaluation of Adaga LifeChit is based directly on the manufacturer's own pre-market clinical investigation data (Study Code: ALP-2021-HM-01-2021/02000) rather than relying on the clinical data of an equivalent device. Consequently, demonstrating formal equivalence under MDR Article 61(5)—which requires a signed contract to access the technical documentation of an equivalent device manufacturer—is not applicable to this regulatory pathway. While the Celox device is acknowledged as a similar device for establishing the state-of-the-art, our conformity is demonstrated through our own clinical evidence.

4.2. Clinical study performed by the manufacturer

4.2.1. General information

Identity of the investigation/study: Study Code: ALP-2021-HM-01-2021/02000.

Identity of the device: Adaga LifeChit Chitosan Based Haemostatic Granules.

Intended use of the device in the investigation: To achieve haemostasis and control bleeding following dental/oral extraction.

Objectives of the study: To prove the haemostatic efficacy and safety of the Adaga LifeChit device.

4.2.2. Study design, participants, endpoints, inclusion and exclusion criteria

Study design: An open-label, prospective, single-arm interventional device study. The follow-up duration was 7 days (up to the suture removal date).

Primary and secondary endpoint(s):

Primary Endpoint: Time to haemostasis from the application of the device on the bleeding area.

Secondary Endpoints: Percentage of subjects achieving haemostasis at 2, 5, 10, 15, and 30 minutes; percentage of subjects with postoperative re-bleeding within 24 hours.

Inclusion/exclusion criteria for subject selection: The study included adult patients (18 years) requiring extraction of a mandibular third molar tooth with mucosal retention. Key exclusion criteria included patients with known shellfish

allergies, pregnant women, patients on anticoagulants/thrombolytics, and patients with underlying coagulation disorders.

40 patients were enrolled and treated. 23 females (57.5%) and 17 males (42.5%). The mean age was 24.4 years, and the mean BMI was 23.78 kg/m2.

4.2.3. Summary of the study and results

Following tooth extraction, the device was applied to the bleeding site. Time to stop active bleeding was measured in seconds. Patients were monitored for adverse events and rebleeding at 1 hour, 2 hours, 6 hours, 24 hours post-extraction, and on Day 7.

The mean time to haemostasis was 117.2 seconds (median: 92.5 seconds). 100% of subjects achieved complete haemostasis by 10 minutes. No postoperative re-bleeding was observed within 24 hours or up to 7 days. Regarding safety, there were 0 serious adverse events. The device was well tolerated; one mild adverse event (facial edema) was reported, but the investigator judged its relationship to the investigational medical device as "unlikely."

4.2.4. Limitations and deficiencies

Limitations of the study: The study was a single-arm design without a concurrent randomized control group, and the clinical model was limited to dental extractions.

Device deficiency and replacements: There were no device deficiencies or device replacements related to safety or performance reported during the study.

4.3. Summary of the clinical data from other sources

4.3.1. Systematic literature review

A systematic literature search was conducted across the PubMed and ScienceDirect databases covering the period from 2013 to 2023. Seven (7) highly relevant clinical studies (including randomized controlled trials and prospective observational studies) were identified, appraised, and included in the clinical evaluation. These studies evaluated the use of equivalent and similar chitosan-based haemostatic dressings (such as Celox and Axiostat) in minor oral surgery, trauma, and pre-hospital emergency settings. The literature data consistently demonstrates that chitosan-based granules achieve rapid haemostasis (often within 1 to 3 minutes) and significantly reduce excessive blood loss compared to conventional gauze. The data confirmed a high safety profile, with no severe device-related adverse events or systemic toxicity reported in the reviewed literature.

4.3.2. Post-market surveillance (PMS), PMCF, and registries

Adaga LifeChit is a new medical device currently undergoing its initial CE-marking under the Medical Device Regulation (EU) 2017/745. Consequently, there is currently no historical post-market surveillance (PMS) data, real-world PMCF data, or medical device registry data available for the device itself. Moving forward, clinical data will be systematically gathered through the established PMCF Plan (TF.01-12.02), which includes proactive data collection via structured user and patient surveys to continuously monitor the device's real-world safety and performance.

4.4. An overall summary of the clinical performance and safety

4.4.1. Clinical performance and documented clinical benefits

The clinical performance of Adaga LifeChit Chitosan Based Haemostatic Granules is demonstrated through its ability to provide rapid, effective haemostasis and prevent excessive blood loss. In a prospective, single-arm clinical investigation evaluating the device following dental/oral extraction (Study Code: ALP-2021-HM-01-2021/02000), the device achieved a 100% success rate for complete haemostasis within 7 minutes, with a mean time to haemostasis of 117.2 seconds. Furthermore, 0% of subjects experienced postoperative re-bleeding within 24 hours. This clinical evidence directly supports the primary clinical benefits of the device: rapidly stopping bleeding and preventing excessive blood loss.

4.4.2. Benefit-risk assessment

Adaga LifeChit is indicated for the control of external bleeding in dental/oral surgery procedures and for the temporary first-aid treatment of life-threatening emergency bleeding (e.g., penetrating trauma, stab injuries, amputations). The expected residual risks and undesirable side effects are rare and generally limited to localized events such as foreign body reactions, inflammatory reactions, minor hematomas, or potential hypersensitivity in patients with known shellfish allergies.

Extensive pre-clinical testing, systematic literature reviews, and our own clinical investigation (which reported 0 serious adverse events) confirm the device's high safety profile. When weighed against the substantial and potentially life-saving clinical benefits of rapidly controlling severe bleeding, these residual risks are deemed highly acceptable. The overall residual design and manufacturing risks are fully acceptable, and the device achieves a high level of protection of health and safety in accordance with the state of the art.

4.5. Ongoing or planned post-market clinical follow-up

In accordance with the latest approved Post Market Clinical Follow-up (PMCF) Plan (TF.01-12.02), PMCF activities for Adaga LifeChit will consist of two primary planned activities to proactively monitor real-world safety and clinical performance:

Annual systematic literature review: A yearly systematic review of scientific and medical databases (e.g., PubMed, ScienceDirect) to continuously monitor the state-of-the-art, evaluate new clinical data for equivalent and similar chitosan-based haemostats, and identify any previously unknown side-effects or emerging risks.

Proactive patient and user surveys: An ongoing, structured PMCF survey study targeting 100 documented device applications. Standardized questionnaires will be distributed to intended users (medical professionals and emergency staff) to evaluate immediate clinical performance (Time to Hemostasis) and usability. Furthermore, a patient follow-up questionnaire will be administered to actively monitor for delayed adverse events (e.g., rebleeding, localized infection, hematoma, or hypersensitivity).

If any emerging risks, complications, or unexpected device deficiencies are detected through these PMCF activities, they will trigger an immediate reassessment of the benefit-risk ratio and be investigated via the manufacturer's Quality Management System CAPA process. The findings of all PMCF activities will be summarized annually in the PMCF Evaluation Report and the Periodic Safety Update Report (PSUR).

4.6. Clinical literature review

Chitosan is a natural polycationic polysaccharide which can be obtained from different sources, e.g., shrimp, crab, squid and certain fungi. It is a multi-functional material with good biocompatibility, no immunogenicity and no skin irritation. In 2001, it was approved by Food and Drug Administration of the United States (FDA) as a GRAS (Generally Recognized as Safe) substance. Currently, a number of FDA-approved chitosan-based hemostatic products including Celox® (MedTrade Products Ltd., Cheshire, UK) TraumaStat® (Ore-Medix, LLC Company, Lebanon, OR, USA) and HemCon® Bandage (HemCon Medical Technologies Inc., Portland, OR, USA) are commercially available. However, it still is a challenge to enhance their hemostatic potential. CS-based composite hemostatic materials refer to a series of novel multi-effect hemostats prepared by combining physically and chemically modified CS and its derivatives with other functional materials. Composite materials have attracted much attention due to their potential synergistic effects that can result in high performance. Therefore, CS-based composite hemostatic materials are becoming more and more extensive in applications. So far, many novel CS-based composite hemostatic materials have been proved to be effective in fast hemostasis and functional hemostasis.

Adverse effects are secondary to incomplete product absorption and local acidity, leading to inflammation and granuloma formation. In addition, neurologic manifestations may result from either direct neurotoxicity or unintended compression of nearby neural structures. Rebleeding can occur following removal of product from the wound bed.

Table 1. First-, Second-, and Third-Generation Chitosan-Based Hemostatic Product Demographics

Product/Manufacturer	Generation	Mechanism of Action	Form	Application
HemCon Bandage HemCon Medical Technologies Portland, OR	First	Cross-links red blood cells (RBCs) to form mucoadhesive barrier	4" × 4" wafer; 2" × 2" single-sided wafer	Placed firmly over wound, 3-min direct pressure
QuickClot Granules Z-Medica Wallingford, CT	First	Rapidly adsorbs water in an exothermic reaction to concentrate clotting factors	Granular zeolite (volcanic rock)	Pour deep into wound, pack standard gauze on top of granules, 3-min direct pressure
ChitoFlex HemCon Medical Technologies Portland, OR	Second	Cross-links RBCs to form mucoadhesive barrier	3" × 9" roll; double-sided	Placed firmly over wound, 3-min direct pressure
Omni-Stat (Celox granules) MedTrade Products Ltd. Crew, UK	Second	Cross-links RBCs to form mucoadhesive barrier	Granular chitosan (3g); 4" × 4" pad	Poured into wound, 3- to 5-min direct pressure
Celox Granules MedTrade Products Ltd. Crew, UK	Second	Cross-links RBCs to form mucoadhesive barrier	Granular chitosan 35g (1.6oz)	Poured into wound, 3- to 5-min direct pressure
Celox-A MedTrade Products Ltd. Crew, UK	Second	Cross-links RBCs to form mucoadhesive barrier	Granular chitosan (6g)	Applied from syringe-like applicator into penetration wound; 3- to 5-min direct pressure
Celox RAPID MedTrade Products Ltd. Crew, UK	Third	Cross-links RBCs to form mucoadhesive barrier	Rolled or Z-fold products, 10' length	Packed into wound, 1-min direct pressure
Celox Gauze MedTrade Products Ltd. Crew, UK	Third	Cross-links RBCs to form mucoadhesive barrier	Rolled or Z-fold products, 3" × 10'	Packed into wound, 3-min direct pressure
ChitoGauze Pro HemCon Medical Technologies Portland, OR	Third	Cross-links RBCs to form mucoadhesive barrier	Z-fold, 12' length	Packed into wound, 2- to 5-min direct pressure

5. Possible diagnostic or therapeutic alternatives

There are several alternative methods available to manage surgical and emergency bleeding, including mechanical methods (direct pressure, sutures, gauze), thermal/energy-based methods (electrosurgery), pharmacological agents, and other topical haemostatic agents (e.g., oxidized regenerated cellulose, gelatine sponges, thrombin products, and fibrin sealants).

5.1. Benefit-risk comparison to alternatives

Mechanical and Thermal Methods: While mechanical methods like direct pressure and sutures are the standard first-line treatment, they may be ineffective for diffuse bleeding or impractical to maintain during severe, life-threatening combat or emergency trauma. Thermal methods (e.g., electrosurgery) are effective in the operating room but require specialized equipment and power sources that are not available in pre-hospital emergency settings.

5.2. Alternative topical haemostats

Passive topical agents (such as collagen or gelatine sponges) rely on the patient's underlying coagulation cascade to achieve haemostasis, which may fail in severely haemorrhaging or coagulopathic patients. Active biological agents (such as bovine thrombin or human fibrin sealants) are highly effective but carry inherent risks of severe immunologic responses, allergic reactions, or potential viral disease transmission, and often require special preparation or temperature-controlled storage.

5.3. Adaga LifeChit (Chitosan)

In comparison, chitosan-based granules function independently of the body's classical clotting cascade by physically cross-linking with red blood cells to form a robust mucoadhesive seal. Adaga LifeChit provides the benefit of immediate readiness (no preparation required), a long shelf life, and avoids the viral and severe immunological risks associated with human or animal-derived active biological agents. The residual risks of chitosan are largely limited to localized foreign body or inflammatory reactions if the granules are not properly irrigated from the wound prior to closure, and potential hypersensitivity in patients with known shellfish allergies.

5.4. Conclusion

When evaluated against available therapeutic alternatives, Adaga LifeChit provides a highly favourable and acceptable benefit-risk profile for the rapid, temporary control of life-threatening emergency bleeding and the management of bleeding during dental/oral extractions.

6. Suggested profile and training for users

Adaga LifeChit Chitosan Based Haemostatic Granules are intended to be used by the following user profiles:

- Lay persons: Who has not get a professional medical training.
- Medical professionals (e.g., Dentists, Oral and Maxillofacial Surgeons): For the control of bleeding during dental/oral surgery procedures. These users must possess standard medical/dental education and clinical experience in haemostatic management and wound care.
- Trained emergency responders/first aid personnel: For the temporary, first-aid treatment of life-threatening emergency bleeding (e.g., penetrating trauma, stab injuries) in pre-hospital settings. These users must possess, at a minimum, certified basic first aid training or emergency medical response education.
- Training requirements: No special device-specific mandatory training or secondary equipment training is required prior to using the device.

However, all intended users must carefully read and fully understand the Instructions for Use (IFU) prior to application to ensure safe and accurate handling. No specific update training is required for the continued safe use of the device.

7. Reference to any harmonized standards and CS applied

Common specification(s) to comply with, if applicable:

No Common Specifications (CS) are currently applicable to this device

Pharmacopiea, International ISO and EN standards (harmonized and other standards as SOTA) to apply, if applicable

- EP monograph 1774 Chitosan hydrocolloid monograph
- EN ISO 13485:2016+A11:2021 Medical devices — Quality management systems —Requirements for regulatory purposes
- EN ISO 14971:2019+A11:2021 Medical devices – Application of risk management to medical devices
- ISO/TR 24971:2020 Medical devices — Guidance on the application of ISO 14971
- EN ISO 10993-1:2025 Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process
- EN ISO 10993-2:2016 Biological evaluation of medical device – Part 2: Animal welfare requirements
- EN ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- ISO 10993-4:2017 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- EN ISO 10993-10:2023 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2021 Biological evaluation of medical devices - Part12: Sample preparation and reference materials
- EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituent
- EN ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process
- EN ISO 10993-23:2021+A1:2025 Biological evaluation of medical devices — Part 23: Tests for irritation
- EN 62366-1:2015+A1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 22422-1:2020 Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management
- ISO 22422-2:2020 Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling
- ISO 22422-3:2017 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents)

Guidance on PMCF and other guidances, if applicable

- MEDDEV 2.7/1 Rev.04 (2016) Clinical Evaluation: A Guide for Manufacturers and Notified Bodies Under Directives 93/42/EEC and 90/385/EEC
- MEDDEV 2.12/1, rev.8 (2013) Guidelines on a Medical Devices Vigilance System January 2013
- MDCG 2020-7 Guidance on PMCF plan template
- MDCG 2020-8 Guidance on PMCF evaluation report template
- MDCG 2020-5 Guidance on clinical evaluation – Equivalence
- MDCG 2019-9 Rev.1 Summary of safety and clinical performance