
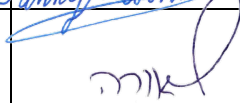


# SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

## POCKET-X GEL

**Eudamed Basic UDI-DI: 7290015384POCKETXGELJQ**

	Name	Title	Signature	Date
<b>Written by</b>	Danny Rosenbaum	Head of RA		29.12.2025
<b>Approved by</b>	Liora Herzlinger	Head of QA		29.12.2025

**Revision History:**

Change control log					
Name	Date	Rev.	List of changes made	Reason for the changes	Training required?
Danny Rosenbaum	28/12/2025	01	Writing a new Summary of Safety and Clinical Performance document.	N/A	No

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**Summary of Safety and Clinical Performance Requirements per the Medical Device Regulation (MDR), Chapter III, Article 32**

This document contains the Summary of Safety and Clinical Performance (“SSCP”) Requirements as required per the Medical Device Regulation (EU) 2017/745, Chapter III, Article 32 and per MDCG 2019-9 (Rev.1) guideline titled “Summary of safety and clinical performance – A guide for manufacturers and notified bodies” dated March 2022.

Pocket-X Gel is an implantable device hence the manufacturer Prudentix Ltd. needs to draw up a SSCP. This SSCP is written in a way that it is clear to the intended user – the dental health care professional (i.e., dentist and dental hygienist) and to the patient.

This document shall be made available to the public via Eudamed and on the manufacturer’s website: [www.prudentix.com](http://www.prudentix.com)

**1. Device identification and general information:**

- 1.1 **Device trade name(s):** Pocket-X Gel
- 1.2 **Manufacturer’s name and address:** Prudentix Ltd., 2 Yodfat Street, P.O.B. 416, Lod 7110401, Israel. Website: [www.prudentix.com](http://www.prudentix.com) . E-mail: [info@prudentix.com](mailto:info@prudentix.com)
- 1.3 **Manufacturer’s single registration number (SRN):** IL-MF-000010034
- 1.4 **Basic UDI-DI:** 7290015384POCKETXGELJQ
- 1.5 **Medical device nomenclature description / text:**  
**Device nomenclature:** none given / none available.  
**Device description:** Pocket-X Gel is a single-use, non-sterile medical device in the form of an in-situ gelling periodontal filler.  
**Device text:** none given / none available.
- 1.6 **Class of device:** Class IIb per Medical Device Regulation (EU) 2017/745, Annex VIII, Chapter III, Rule 8.
- 1.7 **Year when the first certificate (CE) was issued covering the device:** 2019.
- 1.8 **EU Authorised Representative (name and SRN):** MedNet EC-REP GmbH, Borkstrasse 10, 48163 Münster, Germany. SRN: DE-AR-000000002
- 1.9 **Notified Body’s name and single identification number:** Eurofins Product Testing Italy S.r.l., Via Cuornè, 21, 10156 Torino (TO), Italy. Notified Body no. 0477.

**2. Intended use of the device:**

- 2.1 **Intended purpose(s):** Pocket-X Gel is intended to improve the healing of the gingiva and to inhibit bacterial re-colonization in the periodontal pocket. Pocket-X Gel is indicated to be used as an adjunctive treatment after root surface debridement (RSD) for moderate to severe chronic periodontal disease in adults with periodontal

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pockets. It is recommended also as part of the routine periodontal treatment program performed by a dentist.

- 2.2 **Indication(s) and target population(s):** Pocket-X Gel is intended to improve the healing of the gingiva and to inhibit bacterial re-colonization in the periodontal pocket. Pocket-X Gel is indicated to be used as an adjunctive treatment after root surface debridement (RSD) for moderate to severe chronic periodontal disease in adults with periodontal pockets. It is recommended also as part of the routine periodontal treatment program performed by a dentist.

Target population(s): Pocket-X Gel is indicated for use in adults and elderly. Pocket-X Gel is not indicated for use in children and adolescents, since safety and efficacy in these age groups have not been established.

- 2.3 **Contraindications and/or limitations:**

**Contraindications:** Patients with known hypersensitivity to Hyaluronic Acid or to any of the ingredients listed in the composition section. Pocket-X Gel is not indicated for use in children and adolescents, since its safety and efficacy in this age group have not been established.

**Fertility, pregnancy and lactation:** Pregnancy: The safety of Pocket-X Gel in pregnant women has not been established. No controlled clinical trials with Pocket-X Gel have been conducted in pregnant women or in animals. As a precaution: Pocket-X Gel should not be used in women who are pregnant, trying to become pregnant or suspect they are pregnant; and the administration of Pocket-X Gel should be suspended for the duration of pregnancy or until it has been determined that the woman is not pregnant. If administered, the dentist should weigh the expected benefits of the product to the mother against the possible risks to the foetus. Lactation: There are no adequate experimental clinical and animal data on the use of Pocket-X Gel during lactation. As a precaution, women administered with Pocket-X Gel must not breast-feed their infants for a period of 3 weeks after the last administration of Pocket-X Gel. Fertility: There are no human and animal data regarding the effect of Pocket-X Gel on fertility. As a precaution, Pocket-X Gel should not be used in patients trying to conceive. Fertile men and women should use a contraceptive for 3 weeks if Pocket-X Gel is to be administered.

### 3. Device description:

- 3.1 **Description of the device:** Pocket-X Gel is a single-use, non-sterile medical device in the form of an in-situ gelling periodontal filler

**Mode(s) of action:** Pocket-X Gel facilitates its effect via a physical mode of action. It is delivered into the periodontal pocket after scaling or root planing and cleaning of the pocket from plaque. Inside the pocket, the gel acts as a filler for volume restoration, thus physically preventing new bacteria from entering and re-infecting the pocket. The gel is easily applied into the deepest portion of the periodontal pocket by means of a thin plastic tip or a thin flexible brush with a rounded tip that will not traumatize the tissues and ensure better application of the gel at the points which are deepest and most difficult to reach. Using Pocket-X Gel is easy due to

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simple physics; liquid fills pockets better than gel does, yet Pocket-X Gel is a liquid that transforms into a gel and stays at the affected site.

**Design characteristics:** Pocket-X Gel is a medical device in the form of a periodontal in-situ gelling sustained release subgingival delivery system. It is an adjunctive treatment after root surface debridement (RSD) or scaling, to improve the healing of the gingiva and to inhibit bacterial re-colonization in the periodontal pocket and as part of the routine periodontal treatment program performed by a dentist. Thanks to the mucoadhesive properties of the in-situ self-forming gel, it is formed and bulked in the application site and adheres to the mucosal tissues.

**Composition / Ingredient(s):** Each syringe with 1 ml contains water, Poloxamer 407, phenoxyethanol, hyaluronic acid and octenidine hydrochloride.

**Is the device for single use?** Yes. The device is for single use.

**Is the device sterile?** No. The device is not sterile.

**Should the device be sterilized before use?** No. The device should not be sterilized before use.

3.2 **Reference to previous generation(s) or variants if such exist, and a description of the differences:** Not applicable.

3.3 **Description of any accessories which are intended to be used in combination with the device:** The filled syringe (with 1 ml of Pocket-X Gel) is provided with two tips, intended for administration of the gel into the periodontal pocket. Attach to the syringe the preferred dedicated tip that is supplied with the product. There is no clinical difference with which tip you choose to use. Both tips are suitable for use in the same periodontal pockets. The difference is only on the way each tip delivers the gel inside the periodontal pocket. You can switch between the tips to achieve the optimal ease of administration:

Option A: Red coloured tip with a small brush. This is a short length tip with a small brush on its end, which helps to spread the gel in the periodontal pocket.

Option B: Blue coloured tip. This is a long length tip, which enables easier placing of the gel in the inner (deepest) areas of the periodontal pocket.

Each syringe and tip are intended for use on a single patient in one or numerous periodontal pockets. Dispose of the syringe and tips after use according to local regulations. Do not use any gel remaining in a syringe on a different patient.

3.4 **Description of any other devices and products which are intended to be used in combination with the device:** Not applicable.

#### 4. Risks and warnings:

4.1 **Residual risks and undesirable effects:** Some of the patients experience adverse reactions, usually transient, during the first few hours after application of the gel in the periodontal pocket. These may also be due to the mechanical application in the periodontal pocket or as a result of the preceding scaling procedures. The most common undesirable effects are discomfort in the treated area, upper gastrointestinal system disorders in the mouth, and dental, gingival, or oral soft

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tissue reactions. Oral disorders: Toothache, gingival swelling, gingival pain, gingival bleeding, gingival hyperplasia, gingival recession, gingival pruritus, mouth ulceration, sensitivity of teeth.

Other undesirable effects may include skin disorders such as: Hypersensitivity to the product causing allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation and blisters.

Other adverse reactions: In rare cases patients may experience systemic hypersensitivity, anaphylactoid reaction, cellulitis and abscess related to the application site, loss of taste and gingival discoloration.

- 4.2 **Warnings and precautions:** Do not inject! Pocket-X Gel is intended for subgingival application only. Local hypersensitivity reactions such as gingival swelling might occur. Patients should be instructed to seek immediate medical attention if after exposure to the product they develop allergic symptoms such as: skin rash, itching, generalized swelling, breathing difficulties, light-headedness, rapid heart rate, upset stomach or diarrhoea, etc.

**Interactions with other products and other forms of interactions:** There are no known interactions when administering Pocket-X Gel with other oral products or oral treatments. From review of the available literature, it is unlikely that problems will arise from using any other oral products together with Pocket-X Gel. However, it is important that the treating physician is informed and shall carefully consider the use of Pocket-X Gel in combination with other products. As a precaution: Pocket-X Gel should not be used together with other products intended to act on the gums, teeth and in the oral cavity without prior consideration.

- 4.3 **Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable:** Not applicable.

## 5. Summary of clinical evaluation and post-market clinical follow-up (PMCF):

- 5.1 **Summary of clinical data related to equivalent device:** Not applicable.

- 5.2 **Summary of clinical data from conducted investigations of the device before the CE-marking:** A clinical study was conducted in the years 2018-2019, by two periodontists in a single center in Israel. The study objectives were to assess the safety and to evaluate the performance of Pocket-X Gel in the improvement of gingival healing and natural sealing of periodontal pockets in patients with periodontal disease, following scaling and root planing (SRP). The rationale of the study was the hypothesis, that a physical barrier inserted into a pre-cleaned periodontal pocket would assist in maintaining the periodontal pocket clean, thus allowing the gums to properly heal and seal the pockets while preventing further inflammation. The study was designed as an open-label prospective study. Both groups initially underwent SRP on the entire mouth. Following the completion of SRP, one group had one/two of its mouth segments (quadrants) treated with Pocket-X Gel while the contralateral segment(s) served as control (i.e. received only SRP). The clinical study conclusion was, that treatment of periodontitis with SRP supplemented with sub gingival application of Pocket-X Gel achieves better results compared to SRP alone. Pocket-X Gel effectively prevents repopulation of

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periodontal pockets, and enhanced improvements of clinical parameters in chronic adult periodontitis patients over a 6-months period. Probing pocket depth and clinical attachment level measurements show distinctly better results when using Pocket- X Gel with SRP than SRP alone. Moreover, the adjunctive treatment enhanced creeping attachment of the keratinized tissue. Similarly, bleeding on probing and mobility showed better result when using Pocket- X Gel with SRP.

- 5.3 **Summary of clinical data from other sources:** Following review of clinical trials on other products intended for the same or for similar indications, it demonstrated that sub-gingival or intra-pocket applications of hyaluronic acid gel in periodontitis patients were all well tolerated and resulted in improved clinical parameters. In the reviewed clinical trials, no major complications have been reported. Their safety features and efficacy impact have made them a suitable candidate as an adjunct to root surface debridement (RSD), a dental procedure also referred to as scaling and root planning (SRP), in chronic periodontitis patients. In summary, the literature review supports the assertion that substantially equivalent devices to Pocket-X Gel provide a safe and effective method for gingival treatment.
- 5.4 **An overall summary of the clinical performance and safety:** The Pocket-X Gel clinical performance clearly shows, with high statistical significance, that Pocket-X Gel is safe, with very little adverse events recorded when used as intended. Moreover, the clinical data present high efficiency of the device in minimizing the probing pocket depth and ameliorating the attachment level and bleeding index, for patients with moderate to severe chronic generalized periodontitis. The biological safety of Pocket-X Gel was evaluated while consideration was given to the type of patient contact, the potential hazards associated with the materials of construction, *in-vitro* tests results, chemical characterization, biocompatibility testing data, information available in the literature, and the history of clinical use of similar device(s). The available scientific literature supports the efficacy and safety of hyaluronic acid-based products for gingival application. Hyaluronic acid is biocompatible due to its natural source and its use in the field of periodontal therapy is well established. This, combined with the review of adverse events which did not identify any risks or hazards, demonstrate the product's overall safety and effectiveness in gingival and periodontal treatment. Taken together, this clinical data on Pocket-X Gel demonstrates its compliance to applicable general safety and performance requirements of medical device per the Medical Device Regulation (EU) 2017/745.
- 5.5 **Ongoing or planned post-market clinical follow-up:** Prudentix Ltd. constantly inspires to gain experience from the post-marketing phase of Pocket-X Gel in order to constantly learn and improve. Prudentix Ltd.'s quality assurance system holds procedures regulating post-marketing actions, customer-related processes, customer complaints, customer satisfaction, and recall procedure.

## 6. Possible diagnostic or therapeutic alternatives:

Pocket-X Gel is intended to be a follow-on treatment after performing on the periodontal pocket root surface debridement (RSD), a dental procedure also referred to as scaling and root planning (SRP).

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The dental health care professional might decide, following RSD / SRP or taking into consideration the individual patient's situation, that there is no need to use Pocket-X Gel.

**7. Suggested profile and training for users:**

Pocket-X Gel is intended to be used by dental health care professionals (i.e., dentist and teeth hygienist). These personal are familiar with the described use & technical operation of the device.

**8. Reference to any harmonised standards and CS applied:**

List of applicable harmonized standards and/or common specifications:

Standard / Other Directive / Guideline	Version no.
ISO 13485	2016 + A11:2021
EN ISO 14971	2019
EN ISO 15223-1	2021
EN ISO 20417	2021
ISO 10993-1	2025
ISO 10993-5	2009
ISO 10993-10	2021
ISO 10993-11	2017
ISO 10993-17	2023/Amd: 1:2025
ISO 10993-18	2020/Amd 1:2022
ISO 10993-23	2021/Amd 1:2025
CEN ISO/TR 24971	2020
CEN ISO/TR 20416	2020
MEDDEV 2.7/1	Rev 4
Ph. Eur. Monograph 5.1.4	01/2021 : 50104

**9. Revision history:**

SSCP revision No.	Date issued	Change(s) description	Revision validated by the Notified Body
01	28/12/2025	Not applicable. Writing a new Summary of Safety and Clinical Performance.	<input type="checkbox"/> Yes. Validation language: English. <input checked="" type="checkbox"/> No. The SSCP is not yet validated by the NB)