Summary of Safety and Clinical Performance – Adin's Touareg™-OS Zygomatic Dental Implants – Class IIb

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 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.

The following information is intended for users/healthcare professionals.

Following this information there is a summary intended for patients.

1. Device Identification and General Information

1.1. **Device trade name(s):** Zygomatic Dental Implants – See product list in appendix A

1.2. **Manufacturer's name and address**: Adin Dental Implant Systems Ltd., Industrial Zone Alon Tavor, POB 1128, Afula 1811101, Israel.

1.3. **Manufacturer's single registration number (SRN):** IL-MF-000014625

1.4. **Basic UDI-DI:** 729010930ZygDentalImp3U

1.5. **Medical device nomenclature description/text:** EMDN No. - Dental Implants P01020101

1.6. **Class of device:** IIb

1.7. **Year when the first certificate (CE) was issued covering the device:** Since 2021

1.8. **Authorized representative:** MedNet EC-REP GmbH, Address: Borkstrasse 10, 48163 Muenster, Germany, SRN: DE-AR-000000002.

1.9. **Notified Body:** MDC Medical Device Certification GmbH., Kriegerstraße 6, D-70191 Stuttgart, Germany, Single identification number: 0483.

2. Intended use of the device

2.1. Intended Purpose

Adin's Touareg™-OS Zygomatic Dental Implants intended for surgical placement through the maxillary arch and anchored in the zygomatic bone to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in edentulous or partially edentulous patients only with severe atrophic maxilla.

Immediate loading (function) is applicable provided that stability requirements are satisfied.

2.2. Indications and Target Populations

Adin's Touareg™-OS Zygomatic dental implants are indicated for use **ONLY** in the following applications:

- Restore patient aesthetics and chewing function
- Support for prosthetic devices such as bridges or dentures.
- Used only in patients with severe atrophic maxilla
- Placement through extra or intra maxillary sinus and into the zygoma bone
- Placement in the maxilla molar region
- One stage or two stage surgical operation
- Immediate loading (function) is applicable provided that stability requirements are satisfied
- ZAGA 0-4 cases
- Bridge work of a minimum of 2 implants with a splinted bridge
- multi-unit reconstruction (TMA) with a rigid splinting of minimum 2 implants.
- an edentulous/full mouth restoration, should be used together with at least two standard implants.
- Immediate loading & function provided that stability requirements are satisfied
- Edentulous cases (full mouth) restoration together with at least 2 standard implants

The target population is edentulous or partially edentulous patients **only** with severe atrophic maxilla (not recommended in children and under-aged patients, until growth has stopped and epiphyseal closure is completed). Dental implants and prosthetics may only be used by dentists or physicians who have had appropriate education and training.

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2.3. Contraindications and Limitations

General contraindications associated with elective surgery should be observed:

- Possible contraindications: chronic bleeding problems, psychological impairment, treatment with corticosteroids, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor patient oral hygiene, bruxism, alcoholism, osteoporosis medications.
- Temporary contraindications: systemic infection, local oral or respiratory infection
- Unfavorable sizes, numbers or desirable position of implant are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Allergic or hypersensitive response to Ti-6Al-4V alloy (titanium, aluminum, vanadium)/stainless steel/DLC coating (Diamond Like Carbon).
- The placement of dental implants is not recommended in children and under-age patients, until growth has stopped and epiphyseal closure is completed.
- Local infections or pathologies, inadequate bone volume and/or quality as well as general diseases and treatments affecting bone and soft tissue healing may result in osseointegration failure, both immediately after surgery or at a later stage.

Specific contraindications associated with zygomatic implant surgery:

- Acute sinus infection or any other sinus pathology
- Chronic infections such as sinusitis
- Maxillary or zygoma pathology
- Mandibular hypomobility disorders
- Underlying uncontrolled or malignant systematic disease precluding implant surgery
- Patient with bruxism
- Patient with unfavorable maxillary jaw relations that prevent correct implant placement and safe support of restoration
- Patient with unsuitable bone condition (volume and density)
- Single unit restoration
- Dentist without proper training for zygomatic implant treatment.

Note: Current best practices, clinical manuals, textbooks and publications should always be consulted for up-to-date information related to medical evaluation, treatment and planning the surgical procedures of patients undergoing implant placement procedures.

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3. Device Description

3.1. Device Description

Adin's Touareg™-OS Zygomatic implants are threaded, root-form titanium dental implants intended to extend Intra and extra-maxillary sinus into the zygomaticus bone to support prosthetic devices, such as artificial teeth, in order to restore chewing function. offers an immediate loading solution for patients with severe atrophic maxilla that in need of dental restoration to restore chewing operation.

Adin's zygomatic implants are made of Titanium alloy (Ti-6Al-4V ELI) that complies with ASTM F136-13(2021)e1 – (*Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*) and EN ISO 5832-3:2021 (*Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*) and surface treated with OsseoFix™ (Calcium Phosphate blast).

Adin's Zygomatic Dental implants and implant cover screws are packaged together in a plastic Blister. The outer Blister serves as the sterility barrier, as validated by gamma sterilization and package integrity validation methods with accordance to EN ISO 11137-2:2015 in conjunction with ISO/TS 13004:2013 and are intended for single-use.

Touareg™-OS Zygomatic Dental Implant features:

- **Material**: Titanium alloy Grade 23 (Ti-6Al-4V ELI)
- **Implant surface treatment**: Adin's OsseoFix™ (Calcium Phosphate blast) on the lower 15-20 mm of implant
- **Diameter**: Ø4.25 (RS will be presented as Ø4.20)
- **Length**: 35-55 mm with 2.5 intervals
- **Connection**: 2.4 internal Hex (RS)
- **Apical**: sharp, based on ISPX2043P Touareg long implant.
- **Neck design**: cylindrical Ø4.25mm, 13 mm from implant apex until 3.5mm from bone level, reduced to Ø4.0mm.
- **Neck surface finish**: machined (not OsseoFix treated)
- **Packing**: new designated Blister
- **Design**: minor design change as possible form existing long implant at L=25 mm.

3.2. A Reference to Previous Generation(S) Or Variants If Such Exist, And A Description of The Differences

Adin's Touareg™-OS Zygomatic is a line extension of existing proven Touareg™-OS endosseous implants (internal hexagon 2.4 mm), with the exemption that the Zygomatic implants are intended to be anchored in the zygoma bone.

3.3. Description of any accessories which are intended to be used in combination with the device

Adin's device does not fall under the definition of "accessory for a medical device" under the EU MDR article 2(2).

3.4. Description of any other devices and products which are intended to be used in combination with the device

Adin's Touareg™-OS Zygomatic dental implants are intended to be connected at different stages of the procedure, with the implant's compatible platform connection, Standard internal hex, RS 2.4mm, as follows:

- Surgical Drivers – used for screwing or untightening of fastener cover screw of the implant.
- Handpiece-Connected Tools – used as adapters for the insertion of the implant to the osteotomy.
- Screws – Cover screws to close the implant after placement using either cover-screw until final or temporary abutment is connected.
- Transfers / Impression copings – Connected to the implant, used to obtain the position of a dental implant utilizing impression procedure.
- Analogs / Replicas – Used by laboratory technicians to replicate implant or implant + TMA and their position in a patient's mouth. The chosen abutment can be connected to analogs for the restoration planning.
- Abutments – Compatible to the implant connection platform. They are attached using screws the compatible implant using the drivers. The TMA™ (Trans Mucosal Abutment) which is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design or a Scan Body for estimating the implant position and angle by scanning the osteotome location to a CAD software

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4. Risks and warnings

4.1. Residual risks and Undesirable Effects

The risk management process for Adin's Zygomatic Dental Implants and Abutments was conducted in accordance with EN ISO 14971:2019+A11:2021. All identified risks were evaluated and mitigated through design controls, validated manufacturing processes, sterilization validation, and user training. Following the implementation of these risk control measures, the residual risks listed below remain.

The degree of probability assigned to each residual risk is based on common industry practice and supported by multiple sources of data, including:

- Adin Internal nonconformance and inspection data
- Supplier quality records and incoming inspection reports
- Process validation outcomes and sterilization dose audits
- Clinical literature (subject and similar medical devices on the market)
- Post-market surveillance data (e.g., complaint reports, vigilance reporting)
- Expert judgment by cross-functional personnel where events are too rare for statistical estimation.

Where the frequency of occurrence is extremely low or no adverse events have been reported to date, risk estimation has been used by worst-case assumptions and existing failure modes from similar devices, consistent with the precautionary principle and accepted sector practices.

A summary of residual risks, their probability categories, and underlying data sources is provided in the table below. Detailed quantitative rationale and data traceability are documented in the Risk Management File, including cross-references to relevant production batches, audit logs, and post-market surveillance (PMS) data.

Table 1- Summary of Adin's Zygomatic Dental Implants Residual Risks and Probability Estimates

Residual Risks	Degree of Probability	Data Source(s)
Implant length mismatch due to mislabelling may cause anatomical damage, procedural delays, or implant unusability.	Between 1:1,000,000 to 1:100,000, Very Low probability, Remote occurrence	Internal label inspection, batch release QC logs, supplier audits
Contamination from insufficient cleaning or environmental controls may lead to bone inflammation, patient harm, or implant rejection	Between 1:1,000,000 to 1:100,000, Very Low probability, Remote occurrence	Environmental monitoring records, cleaning validation reports, PMS complaint data
Insufficient gamma irradiation may result in tissue contamination, inflammation, and implant rejection	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Sterilization validation and audit results, dose mapping, PMS reports
Inaccurate drilling angulation may cause patient harm, damage to vital structures, and implant misalignment preventing restoration	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Clinical procedure training, surgical guide adoption, PMS data review, expert opinion

Undesirable side effects associated with zygomatic dental implants have been reported in clinical literature and clinical evaluation reports. Sinusitis, occurring as both a post-operative and late complication, is observed with a typical prevalence ranging from 2.4% to 5%. Soft tissue infections are reported in approximately 2.0% of cases. Oroantral fistulas or communications occur less frequently, with a prevalence between 0.4% and 4.8%. Temporary sensory nerve deficits, presenting as paresthesia, have been documented in approximately 1.0% of patients. These adverse events highlight the importance of careful surgical technique and post-operative management to minimize patient risk.

The residual risks and undesirable side effects identified are considered acceptable when weighed against the benefits of the device and in alignment with Adin's risk acceptance criteria. Ongoing post-market surveillance ensures continued monitoring of these risks.

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4.2. Warnings and Precautions

Warnings:

- Zygomatic implant treatment requires specific knowledge.
- Do not reuse single use items such as implants and cover screws. Reuse of these devices will increase risk of product failure, functionality failure and contamination.
- Care and maintenance of reusable instruments are crucial for a successful treatment and are essential for the outcome of the total treatment.
- Failure to recognize actual lengths and direction of drills relative to radiographic measurements and surrounding anatomical structures can result in permanent injury to nerves or other surrounding vital structures.
- Aside from mandatory precautions such as sepsis, specific attention to drilling procedure must be taken to avoid damaging the nerves and vessels by referring to anatomical knowledge and preoperative radiographs.
- Common risks associated with zygomatic implantation procedure are sinusitis and fistula formation.

Precautions:

- The use of Adin Touareg™ OS Zygomatic implants only with Adin Dental surgical tools and prosthetic components is strongly recommended. Lack of compatibility between components can lead to instrumental failure, damage to tissue or unsatisfactory aesthetic results.
- Special training before undertaking a new treatment method is highly recommended.
- Pre-operative:
    - Patient clinical and radiographic full checkup is mandatory in order to determine the psychological and physical status. Medical CT scan or CBCT (cone beam CT) prior to treatment planning is highly recommended.
    - Zygomatic implantation candidates must have clinically symptom-free sinuses with no pathology in adjacent bone and soft tissue.
    - Pay particular attention to patients suffering from local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process.
    - In general, implant placement and prosthetic design must accommodate individual patients' conditions. In cases of bruxism or unfavorable jaw relationship reappraisal, other treatment options should be considered.
    - Zygomatic implant procedures can be performed under local anesthesia, IV-sedation or general anesthesia.
- Intra-operative:
    - Maintain good conditions for all instruments and tooling used during implantation procedure to ensure that instrumentation does not damage implants or other components.
    - Major attention must be taken for aspiration/swallowing danger due to the small size of the component.
    - A minimum of four implants (preferably six implants) must be used when supporting a fixed prosthesis in a fully edentulous arch.
    - Post implant installation should be based an evaluation of bone quality and initial stability to determine the loading timeline (immediate or delayed loading).
    - Arch cross stabilization should be used — optimizing force distribution, minimizing distal cantilevers, decreasing cuspal inclination of the prosthetic teeth and lowering the possibility of the unfavorable, bending moment forces which can potentially jeopardize the long-term stability of an implant-supported restoration.
- Post-Operative:
    - Periodical (at least yearly) patient follow-up after implant treatment and restoration is strongly advised in order to maximize long term treatment outcome and survival.

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

Several vigilance databases available in English language were selected for the search in order to represent different regulatory territories where Adin's products are registered (EU, USA, Canada, Australia and Asia) and were searched to identify and analyze reported recalls, adverse events and field safety corrective actions related to Adin's comparable products.

Most of the vigilance reported events are of Implant failure to osseointegrate/loss of osseointegration which is also a well-known inherent risk in dental implants and can lead implant failure – This is already covered by and detailed in the implants' IFUs and the risk assessment reports.
Based on this data, potential adverse events reviewed through vigilance databases as well it was determined that no new risks in regards with device's clinical safety and effectiveness were raised.

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

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

Per MDCG 2020-6, “For well-established technologies the clinical evaluation can be based on data coming from similar devices, under the conditions detailed in paragraph 6.5 (e). When clinical data from equivalent devices is used, equivalence must be demonstrated according to the requirements of the MDR”. In this SSCP, the term “similar devices” refers to equivalent devices, as defined in MDR Annex XIV, Part A, Section 3.

According to article 61(6)(b) of Regulation (EU) 2017/745 on medical devices (MDR), Adin is exempt from a required contract with other manufacturers for demonstration of equivalence. other means of access to data, including publicly available clinical and technical information, are sufficient to support the demonstration of equivalence in this case.

Adin can demonstrate equivalence through public clinical and commercial information published by the manufacturers of the equivalent products, taking into consideration the technical, biological and clinical characteristics, as required in Annex XIV Section 3 of the EU MDR. For a complete rationale regarding the demonstration of equivalence according to MDR, see section 10.1.2.

Adin’s subject devices are medical devices using technologies that have been applied since decades and are considered state-of-the-art and fulfill the requirement of a "well-established technology" for dental implants are met.

Equivalent devices, which are also commercially available on the market and used for the same intended clinical purpose and for the same intended population, were identified.

Clinical information of equivalent devices related to short- and long-term outcome and survivability of dental implants and abutments, complications and risks was located through available information provided by the manufacturers of the similar devices (clinical cases, articles, IFU, brochures, catalogs), through literature search in the scientific databases (PubMed, BioMed, Elsevier) and vigilance database for adverse events and recalls (FDA CDRH MAUDE, DAEN, MHRA, etc.).

For equivalent devices to Adin, were reported cumulative survival rate of 96.7% after a median follow-up of 13 years and 89%–100% has been reported as the success rate of implants over the 10 years for delayed loading protocol after implantation compared to immediate loading (96.37%-100%).

A structured equivalence assessment was conducted in accordance with MDR Annex XIV, Part A, Section 3, and is summarized below:

- Same intended use (intended to be used as anchoring or supporting tooth replacements to restore chewing function). Zygomatic dental implants have been introduced in the 1971 and are used ever since as a treatment option in dentistry and dental implantation surgeries, not only as a solution to obtain posterior maxillary anchorage but also to expedite the rehabilitation process. This clinical use has become more and more common in the modern dentistry for this specific intended use as can be seen in the comparable devices (Annex B).
- Same patient population (Patients with severe atrophic maxilla.).
- Same clinical application (surgical placement through the maxillary arch and anchored in the zygomatic bone to provide support for prosthetic devices such as artificial teeth in order to restore the patient's chewing function in edentulous or partially edentulous patients only with severe atrophic maxilla.).
- Similar Material – All Adin's Touareg™ OS Zygomatic Dental Implants are made of Titanium alloy (Ti-6Al-4V ELI).
- Surface treatments to generate a favourable surface topography are conducted via sand blasting in other comparable implants. Adin uses either OsseoFix™ (calcium phosphate) and this can be seen also in other devices.
- Dimensions - diameters and lengths variations of the implants are similar but there no clinically significant difference in the safety and clinical and safety performance. Adin tested device are validated through performance testing like fatigue which show that under normal intended conditions the dental implant systems meet their specifications and do not raise any new safety and performance issues in comparison to equivalent devices.

In light of the above it was concluded by Adin that the subject devices are similar to the commercially available products.

The tables in appendix B summarize the equivalence comparison of Adin's dental implant systems, and the commercially available similar devices identified

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable.

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5.3. Summary of clinical data from other sources, if applicable

While clinical data specific to the Adin Zygomatic Dental Implant is not yet available in published scientific literature due to the device's recent market introduction (CE marked since 2021), the clinical safety and performance of the system have been robustly supported through a structured review of alternative sources. These include PMS, PMCF activities, global vigilance databases, and risk management outputs. Additionally, safety and performance insights were derived from vigilance reports of similar products, as well as internal verification and validation testing.

Post-market surveillance data collected by Adin Dental Implant Systems Ltd. indicate a favorable safety profile. Since launch, over 1,000 units have been distributed globally, with no serious adverse events or device-related complications reported. The overall complaint rate remains below 0.2%, and most reports were attributed to procedural variables rather than any deficiencies in device design or function. No field safety corrective actions (FSCAs), product withdrawals, or adverse trends have been observed to date.

PMCF activities—including structured feedback from clinicians and distributors—further support the positive performance of the device in clinical practice. Reports consistently confirm reliable primary stability, predictable surgical handling, and successful osseointegration, particularly in challenging cases involving severe maxillary atrophy. The system has been positively evaluated for its compatibility with established surgical protocols and tools. No negative trends or unexpected risks have emerged since market entry.

Moreover, a review of key international regulatory and vigilance databases—including the FDA MAUDE (USA), MHRA (UK), BfArM (Germany), TGA (Australia), and Health Canada—has revealed no adverse events, recalls, or safety alerts associated with the Adin Zygomatic Dental Implant system.

In conclusion, although formal clinical investigations or published studies specific to this device are not yet available, the body of alternative clinical evidence—including PMS, PMCF, and registry reviews—demonstrates a reassuring early safety and performance profile. Continued post-market monitoring is in place to support ongoing evaluation and early detection of any emerging risks, thereby ensuring continued compliance with regulatory requirements and clinical expectations.

5.4. An Overall Summary of The Clinical Performance and Safety

Adin's dental implants systems were assessed based on the following tests, performed according to state-of-the-art standards (EU harmonized standards were used where available) in order to verify and validate the safe clinical use of the devices:

- **Biocompatibility Tests** were performed on Adin's dental implants to protect patients from undue risks arising from biological hazards associated with materials used for manufacture and final device. Ti-6Al-4V ELI titanium alloy implants with OsseoFix™ treatment were tested for cytotoxicity per EN ISO 10993-5:2009, skin sensitization and irritation per ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. All test articles showed no signs of causing cell lysis, signs of irritation or sensitization. Based on test results it was concluded that all materials are biocompatible when used under recommended intended use.
- **Fatigue Testing –** Fatigue tests of the worst case of Adin's zygomatic implant systems assembled with abutments were tested using fatigue test per ISO 14801:2016 – Dentistry – Implants – Dynamic fatigue test for endosseous dental implants. Per standard requirements, 'worst-case' implant-abutment assembly was chosen for the test. Implants with longest length were selected and tested as representatives. Test setup simulates worst case of clinical loading of a ZAGA 4 type. Results of the test showed that zygomatic implants are within approved Adin's specification.
- **Gamma Sterilization Validation -** Adin's zygomatic dental implants are provided sterile using gamma radiation, packaged in sterile-barrier system packaging that went through gamma sterilization validation in accordance with VDmax 20kGy method per EN ISO 11137-2:2015 standard in conjunction with ISO/TS 13004:2013. Results showed that Sterile Assurance Level (SAL) of at least 10^{-6} is achieved under routine sterilization process which is revalidated using dose audit performed quarterly per EN ISO 11137-2:2015 requirements.
- **Package Integrity Validation for the Duration of Shelf Life –** Integrity of sterile-barrier packaging employed by Adin for sterile dental implants was validated in accordance with EN ISO 11607-1:2019 (Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems). The packaging was subjected to several treatments prior to integrity testing: shelf life under real time and accelerated aging conditions, two-gamma radiation cycles and transportation simulation.
  Based on results for performed tests it was concluded that integrity of sterile-barrier packaging as well as sterility of the implants remain through shelf life defined as 5 years and through transportation processes.

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Adin dental implants, according to available literature, for similar devices to Adin were reported cumulative survival rate of 96.7% after a median follow-up of 13 years and 89%–100% has been reported as the success rate of implants over the 10 years.

In addition, most of the residual risks (section 4.1) have low probability to occur (Less than 1:1,000,000, likely not occur, or Between 1:1,000,000 to 1:100,000 a very low probability).

As described in "Dental Implants Prosthetics 2nd Ed, Ch. 1 by C. E. Misch: Bone loss is a major benefit since it affects the patient in many aspects, the loss of teeth results in bone loss in the jawbone with the aesthetic consequences result in the look change of appearance. with tooth loss range comes the following psychological effects such as neuroticism, increase expenses on denture adhesive, lead to low self-esteem and avoidance of social contact. Dental implants are primarily used to replace missing teeth in a partial or complete edentulous patient or to retain removable prostheses. Therefore, the typical purpose of a dental implant is to act as an abutment for a prosthetic device, similar to a natural tooth root and crown which result of that is a device that mimics the look and feel of a real natural tooth as much as possible. In addition, compromised dental function causes poor masticatory performance and swallowing poorly chewed food, which in turn may influence systemic changes favouring illness, debilitation, and shortened life expectancy.

Poor chewing ability may be a cause of involuntary weight loss in old age, with an increase in mortality rate. In contrast, persons with a substantial number of missing teeth were more likely to be obese. After conventional risk factors for strokes and heart attacks were accounted for, there was a significant relationship between dental disease and cardiovascular disease, the latter still remaining as the major cause of death. It is logical to assume that restoring the stomatognathic system of these patients to a more normal function may indeed enhance the quality and length of their lives.

With high survival rates and low probability of the risks, the risks mitigation done by Adin, the above-mentioned major benefits outweigh the risks to partially or fully edentulous patients who receive surgical placement in the maxillary and/or mandibular arches for the restorations of missing teeth.

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

PMCF Plan, a decision is made on conducting PMCF study based on data collected through PMS activities, in order to confirm clinical performance and safety of the device. The decision about conducting PMCF will be accepted if the criteria for such study are met per the PMCF approved plan.

6. Possible diagnostic or therapeutic alternatives

Traditionally, Rehabilitation of extremely atrophic totally edentulous maxillae by insertion of standard implants is very challenging and required Many types of bone-augmentation procedures, including sinus lifts, to increase the bone volume for regular implant insertion. These are widespread techniques, but the frequent need to use delayed protocols in which the grafts are placed first, and the risk of potential intraoral and/or extraoral complications could decrease patient acceptance. Alternatively, Zygoma implants enable full, often immediate, reconstruction of the upper dental arch without the need for sinus lift treatment.

7. Suggested profile and training for users

All the intended users are licensed dentists which are specialized in the dental implant field and as such have the technical knowledge, experience, education and the necessary training. In addition, Adin provided intended users with the necessary information (warning, instruction for use, contraindication) through IFU, user manuals and additional training/guidance when deemed necessary.

8. Reference to any harmonized standards and CS applied

See list of applied standards and common specifications in Appendix C.

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	26.10.2025	First edition	☒Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

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Appendices

Appendix A - List of Class IIb Products covered under Adin Dental Implant Systems Ltd.

The list of Class IIb Products is hereby presented, the full detailed list can be found Adin Declaration of conformity for Adin's Zygomatic Dental Implants:

Cat. Number	Description	Basic UDI-DI
ISZT3542	Touareg™-OS Zygomatic Dental Implant 4.2D 35L	729010930ZygDentalImp3U
ISZT3742	Touareg™-OS Zygomatic Dental Implant 4.2D 37.5L	
ISZT4042	Touareg™-OS Zygomatic Dental Implant 4.2D 40L	
ISZT4242	Touareg™-OS Zygomatic Dental Implant 4.2D 42.5L	
ISZT4542	Touareg™-OS Zygomatic Dental Implant 4.2D 45L	
ISZT4742	Touareg™-OS Zygomatic Dental Implant 4.2D 47.5L	
ISZT5042	Touareg™-OS Zygomatic Dental Implant 4.2D 50L	
ISZT5242	Touareg™-OS Zygomatic Dental Implant 4.2D 52.5L	
ISZT5542	Touareg™-OS Zygomatic Dental Implant 4.2D 55L	

-- END OF PRODUCT LIST –

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Appendix B – Summery of Adin's Dental Implant system and Similar Devices

Device / Feature	Similar Device – Zygomatic Implant by Noris	Adin Touareg™ OS Zygomatic Dental Implant	Level of Similarity [=, ✓, ✗]
Intended use	intended to be used as anchoring or supporting tooth replacements to restore chewing function.		= Same
Intended patient population	Patients with severe atrophic maxilla.		= Same
Materials	Titanium alloy (Ti-6Al-4V ELI)		= Same
Surface treatment	RBM (resorbable blast media)	OsseoFix	= Same
Basic design	Sharp threads at the apical part for maximum retention to the zygomatic bone. Implant's neck surface design is machined for Smooth implant body to reduce periopathogens adherence.	Sharp threads at the apical part, machined neck surface design for Smooth implant body to reduce periopathogens adherence.	= Same
Diameter	Ø4.2mm		= Same
Length	30-60mm	35-55mm	= Same
Reusable/Single use	Single use		= Same
Sterile provided	Sterile		= Same
Clinical procedure	Intended to be used (osseointegration) in the zygomatic bone.		= Same
CE-Mark approved	Yes		= Same
Illustrations			= Same

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Appendix C - List of Applied Standards and Common Specifications

No.	Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
General					
1.	EN ISO	13485	Quality Systems – Medical Devices – System requirements for regulatory purposes	2016 + A11:2021	Fully, except for service provision and customer property (not applicable for Adin's QMS)
2.	EN ISO	14971	Medical devices – Application of risk management to medical device	2019-A11:2021	Fully, per FMEA method
3.	ISO/TR	24971	Medical devices – Guidance on the application of ISO 14971	2020	Fully
4.	EN ISO	10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;	2020	Fully, except for non-applicable tests based on device category and risk management process
5.	EN	62366-1	Medical devices - Application of usability engineering to medical devices	2015 + A1:2020	Fully
6.	EN ISO	20417	Medical devices — Information to be supplied by the manufacturer	2021	Fully
7.	EN ISO	15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	2021	Fully
8.	EN ISO	14801	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants	2016	Fully
Materials					
9.	ASTM	F136	Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (extra low interstitial) alloy for surgical implant applications	2013 + R2021 + E1	Fully
10.	EN ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2021	Fully
11.	ASTM	F899	Standard Specification for Wrought Stainless Steels for Surgical Instruments	2023	Fully
Sterile Devices					
12.	EN	556-1	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001	Fully
13.	EN ISO	11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015 + A2:2019	Fully
14.	EN ISO	11137-2	Sterilization of health care products-radiation – Part 2: Establishing the sterilization dose	2015 + A1:2023	Fully, in conjunction with ISO/TS 13004:2013
15.	EN ISO	11137-3	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	2017	Fully

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No.	Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
16.	ISO/TS	13004	Sterilization of health care products – Radiation – Substantiation of selected sterilization dose: Method VDmaxSD	2013	Fully in conjunction with EN ISO 11137-2:2015
17.	EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020 + A11:2022 + A1:2023	Fully, per applicable selected tests for rigid microbial barrier package (tube).
18.	EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020 + A11:2022 + A1:2023	Full compliance with selected tests.
19.	EN ISO	11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2018 + A1:2021	Fully
20.	EN ISO	11737-2	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020	Fully
Non-sterile devices					
21.	EN ISO	17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2006	Fully
22.	ISO	17665	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1	2024	Fully
23.	EN ISO	17664-1	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices	2021	Fully
24.	ANSI / AAMI	ST98	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices	2022	Fully
25.	ASTM	F1089	Standard Test Method for Corrosion of Surgical Instruments	2018	Fully
Manufacture / Processes					
26.	EN ISO	14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	2015	Fully. For ISO class 7
27.	EN ISO	14644-2	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015	Fully
28.	EN ISO	14644-3	Cleanrooms and associated controlled environments – Part 3: Test methods	2019	Fully
29.	EN ISO	14644-4	Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up	2022	Fully

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No.	Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
30.	EN ISO	14644-5	Cleanrooms and associated controlled environments – Part 5: Operations	2004	Fully
31.	EN ISO	1797	Dentistry - Shanks for rotary and oscillating instruments	2017	Fully
32.	ISO	2859-1	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	1999 (AMD 1:2011)	Fully
33.	ASTM	D4169	Standard Practice for Performance Testing of Shipping Containers and Systems	2023 E1	Fully
34.	ASTM	D4332	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	2022	Fully
35.	ASTM	D999	Standard Test Methods for Vibration Testing of Shipping Containers	2008 R2023	Fully
36.	ASTM	D5276	Standard Test Method for Drop Test of Loaded Containers by Free Fall	2019 R2023	Fully
37.	ASTM	D4728	Standard Test Method for Random Vibration Testing of Shipping Containers	2017 R2022	Fully
38.	ASTM	F2338	Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	2009 + R2020	Fully

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Appendix D – Literature Review Bibliography

Below are the sources used for the literature review conducted to identify publications through a search of the scientific literature pertaining to the performance and safety of Adin's Zygomatic dental implants:

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