

Federal Communications Commission
Equipment Authorization Branch
7435 Oakland Mills Road
Columbia, MD 21046

Heidelberg, December 16, 2025

Re: Precisis GmbH

Request For Confidentiality

Precisis EASEE® Power - FCC ID 2BSNV-EAPW01 - FCC Part 95 Certification

To whom it may concern,

Precisis GmbH requests that the information contained in the items enumerated below pertaining to the above-referenced application be withheld from public disclosure in accordance with Section 0.459 of the Commission's Rules, 47 C.F.R. § 0.457, following grant of the application. In support of this request, Precisis GmbH submits the following:

1. identification of the specific information for which confidential treatment is sought:

a. identification of exhibits for long-term confidential treatment

- Schematics
- Parts List
- Block Diagram
- Internal Photographs
- Operational Description

The materials set forth in these exhibits, which are segregated from the nonconfidential exhibits of the application, are those for which permanent confidentiality is sought.

b. identification of Exhibits for Short-Term Confidentiality (180 days)

- External Photographs
- Test Setup Photographs
- User Manual

The materials set forth in these exhibits, which are segregated from the nonconfidential exhibits of the application, are those for which short-term confidentiality is sought.

2. identification of the Commission proceeding in which the information was submitted or a description of the circumstances giving rise to the submission:

The proceeding is that involving the application for and certification request for FCC ID 2BSNV-EAPW01.

3. explanation of the degree to which the information is commercial or financial, or contains a trade secret or is privileged:

This information is embodied in circuit diagrams, detailed explanations, parts lists, a block diagram and internal photographs of a completely sealed device designed for implantation in a human body. As such, this material is treated as highly confidential business information and information that could convey trade secrets pertaining to manufacturing and design techniques.

4. explanation of the degree to which the information concerns a service that is subject to competition:

The information for which confidentiality is sought is employed in the design and manufacture of medical implantable devices that are offered on a highly competitive basis. Customers for this equipment have a variety of competing sources of supply from both domestic and foreign suppliers.

5. explanation of how disclosure of the information could result in substantial competitive harm:

Disclosure would, in effect, give away the fruits of the labors of Precisis's engineering personnel, who have designed the equipment and the manufacturing processes. Disclosure would also offer competitors additional unwarranted insight into the state of product development thereby allowing such competitors an advantage that would not be available to Precisis.

6. identification of any measures taken by the submitting party to prevent unauthorized disclosure:

The information for which confidential treatment is sought is kept confidential by Precisis and not made available to third parties except pursuant to arrangements designed to prevent public disclosure.

The circuit board or internal components are not accessible to users. They are enclosed in a titanium housing hermetically sealed by welding. The header is embedded in epoxy. The device cannot be opened without using brute force and destroying the device.

The device is intended to be surgically implanted in the human body and is not accessible to the public.

7. identification of whether the information is available to the public and the extent of any previous disclosure of the information to third parties:

To the knowledge of those preparing this application, the information has not been disclosed publicly heretofore. The protection sought is narrowly drawn and pertains to certain specific implementations of the technology incorporated into the device for which certification is sought.

8. justification of the period during which the submitting party asserts that material should not be available for public disclosure:

While improvements in design are likely to be made during this period, disclosure of the design information would lead to insights into both designs and manufacturing techniques and could have an adverse competitive effect for many years to come. This application contains information that will be used in future applications for similar devices. Moreover, the radio communication aspects of this device are employed in the programming of a medical implant device and in the transmission of highly private medical information to and from the device. Disclosure of the information for which confidentiality is sought could jeopardize the protection of such personal private medical information generated for the benefit of patients into whom the

device has been implanted. As such, it is important that information pertaining to the design and operation of this device not be made available to unauthorized persons who might attempt to use knowledge of the design to compromise the applications for which the equipment will be employed.

The device will be used in an FDA-approved Investigational Device Exemption (IDE) pivotal clinical study prior to Premarket Approval (PMA) submission. Until surgical implantation the devices are kept under lock and key. Premarket approval for commercial distribution is expected no earlier than three years after FCC approval. Under FCC rules (47 CFR §2.803), the investigational use does not constitute marketing. Therefore, short-term confidentiality extends until commercial distribution begins.

9. any other information that the party seeking confidential treatment believes may be useful in assessing whether its request for confidentiality should be granted:

See item 8 above. Note that the equipment for which approval is being sought will be employed in applications that inherently carry a premium on security.

When the device is marketed, Precisis GmbH will inform the TCB to release the short-term confidentiality information withheld on the FCC equipment authorization website.

Respectfully submitted,

**Christian
Marcel
Wessinger**

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Signature
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Senior Supply Chain Manager
Precisis GmbH