

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

Heidelberg, January 26, 2026

Re: Precisis GmbH

Request For Confidentiality

Precisis EASEE® Communicator - FCC ID 2BSNV-EACOM01 - FCC Part 15 and Part 95 Certification

Ladies and Gentlemen,

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. long-time confidentiality is requested for:
 - Schematics
 - Parts list
 - Block diagram
 - Operational description
 - Internal photographs
- b. Short-Term Confidentiality (180 days) is requested for:
 - External photographs
 - Test setup photographs
 - User manual

Should U.S. commercial marketing or public availability not commence within the short-term confidentiality period, Precisis GmbH will promptly notify the Telecommunication Certification Body (TCB) in accordance with FCC procedures.

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-EACOM01.

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

The information is embodied in circuit diagrams, detailed explanations, parts lists, and block diagrams. These materials are treated as highly confidential business information and contain trade secrets related to manufacturing and design techniques. The parts list includes proprietary component selection and sourcing strategies that are critical to device performance and competitive differentiation. Internal photographs reveal circuit topology and component placement that directly reflect these confidential design choices.

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 device communication equipment operating in a highly competitive global market. Domestic and foreign manufacturers offer functionally similar systems, and product differentiation is strongly dependent on proprietary electronic and RF design implementations.

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

While the device is commercially available in the European Union, the exhibits submitted in this FCC application disclose implementation-level RF design, component selection, manufacturing processes. Public disclosure would enable competitors to analyze and replicate proprietary design and manufacturing approaches without incurring comparable development costs, resulting in substantial competitive and economic harm to Precisis GmbH.

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

Precisis GmbH maintains strict internal controls governing access to proprietary technical documentation, including schematics, RF design data, internal photographs, and component information, which are disclosed only to authorized personnel and covered by formal confidentiality obligations.

While devices are commercially available in the EU, devices provided in the United States are distributed exclusively within a controlled clinical study environment. A portion of the devices is provided to authorized clinical investigators under confidentiality obligations, and a portion is provided to study participants for personal therapeutic use.

Study participants do not receive access to confidential technical documentation and are provided only user-level operational information. Internal components are not visible during normal operation, and no service manuals, instructions, or tools for accessing internal components are provided to patients or the public.

User information and informed consent materials instruct participants not to modify, open, or disassemble the device from its delivered condition and warn that unauthorized modification may result in unsafe conditions, loss of functionality, shortened battery life, or other unintended effects.

In addition, participants receive a voluntary request to respect the confidentiality of the research study, including not sharing study materials, investigational device details, or unpublished study information publicly or via social media during the study. This request does not impose confidentiality obligations and does not limit participants' rights to discuss

their participation with family members, caregivers, healthcare providers, or to report concerns or adverse events to the study team, an Institutional Review Board, or regulatory authorities.

While the device housing can be mechanically opened using tools, doing so requires deliberate action outside the scope of normal use and contrary to the provided safety instructions. Accordingly, confidential technical information submitted to the FCC is not intentionally disclosed or made routinely available 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:

While certain high-level product information is available in the EU, the exhibits submitted to the FCC – including detailed schematics, block diagrams, and operational descriptions – remain confidential. Although the physical devices are commercially available in the EU, in the U.S. the devices will be used exclusively in a controlled environment (FDA-approved IDE pivotal clinical study prior to PMA submission).

The internal photographs submitted for FCC certification are not routinely available to the public. Precisis GmbH does not publish, distribute, or otherwise make available internal photographs or internal design information.

Although a determined individual could physically access internal components by intentionally opening the device, such access requires deliberate misuse beyond normal operation and does not constitute routine public availability within the meaning of 47 CFR §0.457(d). The availability of a sealed device to study participants for therapeutic use does not equate to public disclosure of internal design information.

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

Permanent confidentiality is requested for eligible exhibits under FCC rules. Disclosure would reveal proprietary circuitry and manufacturing techniques, causing significant competitive harm.

In the US, the devices will be used exclusively in an FDA-approved IDE pivotal clinical study prior to PMA submission. Approximately 200 patients will be enrolled across multiple U.S. sites under controlled conditions. The study is expected to start after FCC grant and continue for at least three years before PMA submission, far exceeding the 180-day short-term confidentiality period.

Under 47 CFR §2.803, investigational use does not constitute marketing; therefore, confidentiality remains valid 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. Additionally, the equipment for which approval is sought will be used in applications that require a high level of security and reliability, including implant programming and transmission of sensitive medical data. These factors underscore the critical need for confidentiality to protect patient safety and prevent unauthorized access to proprietary communication protocols.

When the device enters commercial distribution, 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
Christian Wessinger
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Precisis GmbH