



Planning for the complete development of Apollonia up to market readiness



1. Expected regulatory classification

Apollonia is expected to be classified as medical device software within the meaning of the EU Medical Device Regulation MDR 2017/745, because the software:

-) clinical data processed
-) provides diagnostic and/or therapeutic options,
-) Supports treatment and design decisions,
-) CAD/CAM results are generated or influenced,
-) conducts quality checks,
-) controls the manufacturing processes of dental restorations.

According to MDR Rule 11, software whose information is used for diagnostic or therapeutic decisions is regularly classified as at least Class II.a. If a potential incorrect decision leads to surgical intervention or a serious deterioration of health, Class II.b may apply. This may include implant planning, surgical procedures, or fully automated treatment decisions. The current European software guideline is MDCG 2019-11 Rev. 1 from June 2025. [EU Commission: Classification of medical device software](#)

Therefore, my recommendation would be:

Apollonia should initially be developed with a clearly defined purpose as Class II.a software . Particularly high-risk surgical or fully automated functions should be addressed as later, possibly separately certified modules.

2. Development to market readiness

The phases partially overlap. Overall, a duration of approximately 36 months is realistic.

phase	Period	Result
1. Product definition and regulatory strategy	Months 0-4	Intended purpose, classification and product requirements
2. Quality and Compliance System	Months 2-12	MDR-compliant quality management and development processes
3. Software Development	Months 4–28	Functional platform including AI and CAD/CAM
4. Verification and clinical validation	Month 18–32	Proof of safety, performance and usability
5. CE Conformity Assessment	Months 28–36	Certificate, CE marking and EU market access
6. Production release	Months 34–36	Commercially available, market-ready version

3. Detailed cost breakdown

These figures are net planning values for specialized German development, medical device, and consulting companies. German software agencies often charge around €120 to €180 per hour; specialized AI, cybersecurity, and MDR experts may charge more. [Market overview: Software development](#), [MDR consultant hourly rates](#)

Phase 1: Product definition and regulatory preparation

work package	Net
Medical purpose and product delimitation	€35,000

work package	Net
MDR classification and regulatory strategy	€35,000
Clinical and dental process analysis	€70,000
System and product requirements	€70,000
Technical feasibility and architectural prototype	€140,000
IP, data protection, contract and procurement structure	€50,000
<u>Phase 1 total</u>	<u>€400,000</u>

Phase 2: Quality Management and Compliance

work package	Net
Structure of the quality management system according to ISO 13485	€120,000
Development process according to IEC 62304	€110,000
Risk management according to ISO 14971	€70,000
Usability according to IEC 62366-1	€60,000
GDPR, data protection impact assessment and contract documents	€65,000
Cybersecurity, Threat Modeling and IEC 81001-5-1	€100,000

work package	Net
AI Act compliance and AI data governance	€85,000
Internal audits, training and PRRC preparation	€40,000
<u>Phase 2 total</u>	<u>€650,000</u>

External consulting firms often quote between €10,000 and €35,000 for simply setting up an ISO 13485 system. However, Apollonia also includes MDR, AI, software, risk, and cybersecurity processes, which is why the overall cost is significantly higher. [Example costs for ISO 13485 consulting.](#)

Phase 3: Technical Software Development

work package	Net
Secure cloud, backend and platform architecture	€600,000
User interface and UX for practice and laboratory	€300,000
Interfaces to practice management systems and APIs	€300,000
Intraoral scan, DICOM, DVT/CT and 3D data processing	€400,000
AI/ML models, computer vision and training pipeline	€650,000
CAD/CAM and design modules	€500,000
Laboratory and production control	€300,000

work package	Net
User, role, rights and audit management	€180,000
DevOps , CI/CD and automated testing	€140,000
Technical project management and product ownership	€130,000
<u>Phase 3 total</u>	<u>€3,500,000</u>

The following technical interfaces should be taken into account at a minimum:

-) DICOM for medical image data
-) STL, PLY and OBJ for three-dimensional model data,
-) HL7 FHIR for structured health data,
-) VDDS or interfaces of the practice management systems,
-) APIs from scanner and CAD/CAM manufacturers,
-) secure laboratory and manufacturing interfaces,
-) Audit-proof logging of all clinically relevant decisions.

4. Testing and medical validation

work package	Net
Independent software verification and validation	€220,000
Penetration tests and cybersecurity audits	€120,000
Formative and summative usability validation	€80,000

5. CE marking and market authorization

work package	Net
Completion of the technical documentation according to MDR	€100,000
Notified Body: Application, QMS audit and document review	€130,000
ISO 13485 certificate and certificate management	€25,000
UDI, EMDN, SRN and EUDAMED registration	€20,000
Labeling, instructions for use and translations	€35,000
Post-Market Surveillance, PMCF and Vigilance System	€70,000
Production release, hosting and emergency validation	€70,000
<u>Phase 5 total</u>	<u>€450,000</u>

For Class II.a and II.b, a Notified Body must audit the quality management system and selected parts of the technical documentation. A Notified Body is a government-designated, but economically independent, auditing organization. [EU Commission: Notified Bodies](#)

TÜV SÜD, for example, publishes the following standard fees:

-) Audit and QMS review: 320 euros per hour,
-) Technical documentation review: 430 euros per hour,
-) Clinical evaluation: 430 euros per hour,
-) Application fee: 2,550 euros.

The actual total price depends on the scope of the inspection and the number of hours required. [TÜV SÜD: MDR fees](#)

6. Risk reserve

position

Net

Reserve for subsequent requests, additional interfaces, repeat inspections and technical delays €500,000

This reserve should not be fully allocated. It provides protection against, in particular:

-) Subsequent requests from the notified body,
-) additional clinical data requirements
-) Problems with scanner and CAD/CAM interfaces,
-) higher requirements of the AI Act,
-) Repeating cybersecurity or usability tests,
-) Changes in regulatory requirements during the three-year development period.

7. Total costs including VAT

Cost block	Net	19% VAT	Gross
Product definition and regulatory strategy	€400,000	€76,000	€476,000
Quality management and compliance	€650,000	€123,500	€773,500
Software development	€3,500,000	€665,000	€4,165,000
Testing and medical validation	€900,000	€171,000	€1,071,000
CE marking and market readiness	€450,000	€85,500	€535,500

Cost block	Net	19% VAT	Gross
Risk reserve	€500,000	€95,000	€595,000
<u>total</u>	<u>€6,400,000</u>	<u>€1,216,000</u>	<u>€7,616,000</u>

The standard German VAT rate is 19 percent. [§ 12 VAT Act](#)

For Apollonia GmbH, which is entitled to deduct input tax, VAT does not normally represent a final cost. It may have to be paid initially, but can subsequently be claimed as input tax. Therefore, the investment requirement should normally be stated to investors as €6.4 million net.

8. Required approvals and documentation

Mandatory or likely to be mandatory

1. Determination of the medical purpose
2. MDR classification according to Rule 11
3. Quality management system according to MDR and ISO 13485
4. Risk management according to ISO 14971
5. Software lifecycle according to IEC 62304
6. Usability according to IEC 62366-1
7. Product safety according to IEC 82304-1
8. Cybersecurity according to MDCG 2019-16 and IEC 81001-5-1
9. Clinical evaluation according to MDR Article 61
10. Technical documentation according to MDR Annex II and III
11. Examination by a notified body
12. EU Declaration of Conformity
13. CE marking

14. UDI allocation and EMDN classification
15. Registration of the manufacturer and product in EUDAMED
16. Appointment of a responsible person pursuant to MDR Article 15 – PRRC
17. Post-Market Surveillance and Vigilance System
18. GDPR and Data Protection Impact Assessment
19. AI Act compliance for high-risk medical AI
20. German instructions for use and safety information

Since May 28, 2026, the EUDAMED modules for actor registration, UDI/product registration, and certificates have been mandatory. [EU Commission: EUDAMED](#)

A valid European CE marking is also valid in Germany; generally, no additional German product approval is required. [BfArM: Medical devices and CE marking](#)

9. Additional requirements due to AI and health data

AI-based medical devices can fall under both the MDR and the AI Act simultaneously. The requirements complement each other. These include, in particular:

-) documented quality of training, validation and test data,
-) Detection of potential distortions,
-) Transparency and traceability,
-) human supervision,
-) Logging,
-) Robustness and accuracy,
-) Cybersecurity,
-) Ongoing monitoring of AI performance.

The European Commission explicitly confirms that the MDR and the AI Act can apply concurrently to AI-based medical devices. [MDCG 2025-6: Interaction of the MDR and the AI Act](#)

Since Apollonia is expected to be market-ready by 2029, the European Health Data Space (EHDS) must also be taken into account. Key aspects apply from March 2029 and concern, among other things, interoperability, data export, access control, and the logging of electronic health data. [EU Commission: EHDS Timeline](#)

10. Special permits not automatically included

The following procedures are only required if Apollonia offers corresponding functions:

Additional procedures	When is it necessary?	Additional net costs
Formal clinical trial	If existing clinical data are insufficient	€300,000–1,200,000
Upgrading to class II.b	In the case of serious therapeutic or surgical decisions	€250,000–€650,000
Gematik/TI procedure	With direct integration into telematics infrastructure or ePA	€100,000–350,000
DiGA procedure at the BfArM	Only if reimbursement is planned as a digital health application	€150,000–€500,000
Additional EU language versions	Depending on the number of target markets	€30,000–100,000
Certification for USA/Canada	Not included in the EU calculation	separately

Direct approval from Gematik is not required if Apollonia communicates solely via approved practice management systems or their interfaces. However, separate testing and approval costs are incurred for a proprietary telematics infrastructure (TI) service or an electronic patient record (ePA) component. Gematik, for example, publishes fees ranging from €10,600 for an integrated KIM client module to €62,000 for an ePA record system – in each case, plus development and testing costs. [Gematik fee schedule](#)

Result

For Apollonia, an investment requirement of 6.4 million euros net for a three-year development period until market readiness is a reasonable planning figure.

With 19 percent VAT, the calculation is as follows:

€6,400,000 net
+ €1,216,000 VAT
= €7,616,000 gross

If classified as Class II.b and undergoing extensive clinical testing, the actual total requirement could rise to approximately 7.0 to 8.25 million euros net or approximately 8.33 to 9.82 million euros gross.