Review Report — Review Package „CardioGuard CG-200“

Sample report on a fictional demo body of material — structure and depth match the real delivery.

0. Report metadata (audit-trail header)

Field	Value
Client	Medlinea GmbH (fictional, demo)
Reviewed material	CardioGuard CG-200, Dossier v1.3: 15 SYS, 14 SW, 5 RC, 10 TC, glossary
Input versions	CardioGuard CG-200, Dossier v1.3 (SHA-256: 3fc837c5…, handed over 2026-06-11)
Intake check	passed on 2026-06-11 (record EC-2026-3fc837)
Package class	S — 29 requirements · 10 test cases · 5 risk controls → lead time 14 calendar days from a passed intake check
Review rule set / pipeline	PRS-MED 2.1 + PRS-LLM 1.3 / PDS pipeline 0.1.0
Human review stage	R. Reisener, Systems Engineering — completed 2026-06-11
Status	**Fully worked-out deliverable** — for internal review and decision support; review and formal release rest with the client

1. Result on one page

Material with a clear ID scheme and predominantly measurable acceptance criteria — but 4 priority-A points that should be resolved before the next review. Without remediating them, central product and risk statements cannot be substantiated, and both the review and the verification phase run into avoidable iterations. Reviewed with the rule set and the semantic review stage; several points were reported independently by both and consolidated.

Concretely blocked until remediation: the evidence for the core function (TC-003 cannot pass against SYS-007/SW-009), the verification planning of risk control RC-04, and a dependable data-protection statement towards operators (**A-03**, **B-07**).

The top 4 review points:

	Review point	Why it matters
● **A-01**	Event signalling ≤ 5 s (SYS-007) is not achievable with 10-s analysis blocks (SW-009)	Affects the core function per intended purpose; TC-003 would never pass this way
● **A-02**	Required 72 h recording (SYS-003) collides with the binding platform specification PF-A2: battery designed for 48 h (SYS-011)	The conflict sits in a platform specification inside annotation text — a classic review slip; additionally blocks TC-002
● **A-03**	"All patient data AES-256 encrypted" (SW-004) vs. plaintext CSV export (SW-012)	Data-protection / security relevant; affects RC-05
● **A-04**	Risk control RC-04 without an implementing requirement	Evidence of risk control per ISO 14971 cannot be established

Review-point balance: 62 pipeline points → 60 confirmed, consolidated into 17 review-point positions (4 A · 8 B · 5 C) → 2 rejected by the human review stage and transparently disclosed (section 5).

Scope of this report: 6 of 7 review categories; category 7 (change impact) not commissioned, as only one version was handed over.

Multimodality scope: purely textual material; no non-textual content detected.

Status: Fully worked out — for internal review; assessment and formal release rest with you.

2. Review points by category

Category	A	B	C
1 Unambiguity	–	–	2
2 Testability	–	2	–
3 Consistency	3	1	1
4 Completeness (reference structure)	–	2	–
5 Term consistency	–	–	2
6 Traceability	1	3	–
7 Change impact	not commissioned		

3. Review points in detail

Priority A — resolve before the next review

Review point	Category	Location	Description & rationale	Correction proposal
A-01	Consistency	SYS-007 ↔ SW-009	Event signalling ≤ 5 s not achievable with 10-s analysis blocks (worst case: event at block start → detection at the earliest after 10 s + processing). Cross-layer conflict system ↔ software.	Switch the analysis cycle to a sliding window ≤ 2 s (SW-009) OR clinically re-evaluate the latency requirement (SYS-007); document the decision in risk management.
A-02	Consistency	SYS-003 ↔ SYS-011 (platform spec) · TC-002	72 h recording duration required; the platform specification PF-A2 declared binding in SYS-011 (requirements spec ch. 4.2, release 2.0) designs the battery for 48 h — deviation only via a platform change request. The conflict is not in the requirement texts themselves but in the specification note — the pipeline reviews annotations as well. The semantic review stage independently reports the consequence for verification: TC-002 tests against ≥ 72 h and cannot pass with the specified platform battery.	Clarify the target value (market/clinical requirement); raise a platform change request or adjust SYS-003; update derived quantities (mass ≤ 90 g) and TC-002.
A-03	Consistency	SW-004 ↔ SW-012	Full-encryption claim collides with the plaintext CSV export of episodes (patient reference after assignment per SW-001). See also **B-07** (conflict with the pseudonymisation concept).	Specify SW-012: export only pseudonymised or encrypted/password-protected; regulate the exception explicitly, update RC-05.
A-04	Traceability	RC-04	"Signal quality index" risk control without an implementing requirement — exists only in the risk file; risk control (ISO 14971) cannot be evidenced. Reported independently by the rule set and the semantic review stage (4 raw points consolidated): the missing implementation makes the control both untestable and unspecified.	Create an SW requirement "signal quality index + artefact flagging", link it to RC-04, derive a test case.

Priority B — close before the verification phase

Review point	Category	Location	Description & rationale	Correction proposal
B-01	Traceability	SW-010	Core performance requirement (QRS sensitivity ≥ 99.0 %, MIT-BIH) without an assigned test case.	Create a test case "algorithm validation against MIT-BIH" (methodology per IEC 60601-2-47).

Review point	Category	Location	Description & rationale	Correction proposal
B-02	Traceability	TC-007	Test case references SW-016 — does not exist. Orphaned test or missing requirement (trend view). Reported independently by the rule set and the semantic review stage (3 raw points consolidated).	Clarify: is a trend view required? Yes → add the requirement; no → remove TC-007.
B-03	Completeness	Dossier overall	IEC 62366-1 declared (section 1), but no usability requirements in the material. Also reported independently by the semantic review stage.	Add a usability block (at minimum: event acknowledgement, electrode handling, status interpretation by patients).
B-04	Completeness	SYS-014	Reference to REQ-EMV-03 (legacy v0.9) not resolvable in the current scheme — EMC test severities effectively unspecified. Typical migration remnant after renumbering. Reported independently by the rule set and the semantic review stage.	Migrate the reference to the current EMC requirement or create a new requirement with test severities (IEC 60601-1-2); scan the legacy material for further old references.
B-05	Testability	SW-006	"Intuitive and easy to operate" not verifiable — no criterion, no method. Reported independently by the rule set and the semantic review stage.	Replace with measurable usability targets (task success rate / operating time for critical tasks, IEC 62366-1); merge with **B-03**.
B-06 (collective point)	Traceability	SYS-002 · SW-007 · SW-011 + more (coverage matrix)	Collective point "missing test-case assignment": requirements without a test link, prioritised by criticality — SYS-002 (alarm sound pressure = risk control RC-01!), SW-007 and SW-011 (security). Full itemisation: coverage matrix (section 4) — each item was reviewed individually; the bundling serves readability only.	Complete the coverage planning, starting with the three named; coordinate the order with **B-08** (acceptance criteria first, then tests).
B-07	Consistency	SYS-010 ↔ SW-012 (· SW-001)	SYS-010 and RC-03 establish a pseudonymisation concept (patient assignment exclusively in the analysis software); however, SW-012 allows the CSV export of episodes after assignment — personally identifiable data leaves the protected context. Independent of **A-03**: even with encrypted export, the conflict with the assignment concept would remain. Point from the semantic review stage.	Document the data-flow concept; restrict SW-012 to pseudonymised export or explicitly regulate re-identification in the export; resolve together with **A-03**, update RC-03/RC-05.
B-08 (collective point)	Testability	SW-001 · SW-003 · SW-005 · SW-007 · SW-008 · SW-011 · SYS-008 · SYS-012 · SYS-013 · SYS-015	Collective point from the semantic review stage: ten requirements without a measurable acceptance criterion or with non-operationalised key terms (incl. "tamper-proof", "functional impairment", "graduated access rights", "be qualified", "faulty or incomplete"). Each item reviewed individually and documented with rationale in the raw-point record.	Add a metric, method and threshold per requirement; safety-relevant ones first (SW-008, SW-011, SYS-008); coordinate with **B-06** — criteria before test derivation.

Priority C — fix at the next revision

Review point	Category	Location	Description & rationale	Correction proposal
C-01	Terminology	SW-003 vs. glossary	"Event" used instead of the defined glossary term "Ereignis"; the semantic review stage additionally reports the term drift at material level.	Unify terminology.
C-02	Terminology	SW-001, SW-012	"Episode" used, undefined in the glossary.	Add a glossary entry or replace the term.

Review point	Category	Location	Description & rationale	Correction proposal
C-03	Consistency	SYS-005 vs. SYS-007	Latency asymmetry 10 s vs. 5 s — not a contradiction, but unjustified.	Document the design rationale or harmonise.
C-04	Unambiguity	SYS-009 vs. TC-008	LED thresholds (80/40/10 %) defined only in the test, not in the requirement. Reported independently by the rule set and the semantic review stage (3 raw points consolidated).	Specify the thresholds in SYS-009.
C-05 (collective point)	Unambiguity	SW-010 · SW-013 · SYS-005 · SYS-007	Collective point from the semantic review stage — four specifications with multiple readings: reference time "after its occurrence" (SYS-007), definition "electrode detachment" (SYS-005), reference quantity of the 90 % storage warning (SW-013), test-protocol details of the MIT-BIH validation (SW-010).	Specify definitions or extend the glossary; explicitly define reference quantities and start points.

4. Coverage matrix

Element	Test	Risk link	Status
SW-001	–	RC-03	**test missing (B-06)**
SW-002	TC-004	–	covered
SW-003	–	–	**test missing (B-06)**
SW-004	TC-005	RC-05	covered (conflict **A-03** open)
SW-005	–	–	**test missing (B-06)**
SW-006	–	–	**test missing (B-06)**
SW-007	–	RC-05	**test missing (B-06)**
SW-008	TC-006, TC-010	RC-02	covered
SW-009	–	–	**test missing (B-06)**
SW-010	–	–	**test missing (B-01)**
SW-011	–	–	**test missing (B-06)**
SW-012	–	–	**test missing (B-06)**
SW-013	TC-009	–	covered
SW-014	–	–	**test missing (B-06)**
SYS-001	TC-001	–	covered
SYS-002	–	RC-01	**test missing (B-06)**
SYS-003	TC-002	–	covered (conflict **A-02** open)
SYS-004	–	–	**test missing (B-06)**
SYS-005	–	–	**test missing (B-06)**
SYS-006	–	–	**test missing (B-06)**
SYS-007	TC-003	–	covered (conflict **A-01** open)
SYS-008	–	–	**test missing (B-06)**
SYS-009	TC-008	–	covered
SYS-010	–	RC-03	**test missing (B-06)**
SYS-011	–	–	**test missing (B-06)**
SYS-012	–	–	**test missing (B-06)**
SYS-013	–	–	**test missing (B-06)**
SYS-014	–	–	**test missing (B-06)**
SYS-015	–	–	**test missing (B-06)**
RC-04	–	–	**no implementing requirement (A-04)**
TC-007 → SW-016	–	–	**orphaned (B-02)**

5. Review-stage transparency: rejected pipeline points

The pipeline reported 62 points; 2 were rejected in the human review:

Pipeline point	Reason for rejection	Lesson learned
Potential contradiction: ingress-protection requirement (SYS-006) vs. exposure to cleaning/disinfection fluid (SYS-008). (SYS-006 (IP54) ↔ SYS-008 (wipe disinfection))	No conflict: ingress protection and disinfection resistance are independent properties that can be met at the same time.	Rule set refined: protection-rating / cleaning pairs are no longer reported as conflict candidates (rule R-WID-90 deactivated in PRS-MED 2.1.1).
Requirement SYS-001 without test coverage. (SYS-001)	Mapping error: TC-001 covers SYS-001.	Assignment logic corrected — feeds into all subsequent reviews.

Standard part of every delivery: rejected points document how the review stage works; every rule update improves future reviews.

6. Inventory figures (neutral)

34 reviewable elements (15 SYS · 14 SW · 5 RC) · 10 test cases · 17 confirmed review-point positions · traceability coverage requirements→tests in the handed-over material: 28 % (8 of 29). (Deliberately without industry benchmarks: dependable comparison corridors arise from real customer projects and are only disclosed then.)

7. Audit trail (short form)

2026-06-11 material intake (SHA-256 record) → 2026-06-11 intake check passed (EC-2026-3fc837) → 2026-06-11 pipeline run (PRS-MED 2.1 + PRS-LLM 1.3 / PDS pipeline 0.1.0; 62 raw points) → 2026-06-11 human review: 60 confirmed (consolidated into 17 positions), 2 rejected, prioritisation, correction proposals → 2026-06-11 delivery (fully worked-out deliverable; release rests with the client). Full machine record: audit trail (JSONL, hash chain).

Note on status: This report is a fully worked-out deliverable for internal review and decision support. Assessment, implementation of the correction proposals and formal release rest with the client within its QM system. The report makes no statements about approvability or audit results.

Meridianfold · Technical documentation as a service for medical technology · kontakt@meridianfold.com