Product Release Readiness Assessment

Regulatory Assessment Report

Determine your product's regulatory release readiness, identify missing evidence and prioritize the actions needed before market launch.

Case	Assessment date	Sample created on
SYNTHETIC SAMPLE – NOT OFFICIALLY ISSUED – IV-240 Variant B	2026-10-30T09:20:00+01:00	2026-10-30

Your product and market scenario

Synthetic release-readiness sample – not a real assessment. Control of industrial test and automation processes in commercial facilities

Subject / requirement	Status
Target markets	DE, AT
Planned market event (customer-reported)	2026-12-16
Confirmed release blockers	2
Assessed objects / configurations	IV-240 / CFG-B2

Assessment result for your case

NOT READY

At least one confirmed release-critical evidence or validity gap prevents product release. The confirmed release blocker remains in effect; other facts or external procedures remain separately unresolved. Route and legal-source acceptance have not been confirmed for every relevant route in this case.

Assessment closure: Open facts

Required checks and next steps

1. Verification required **Complete EMC test/standards evidence, technical documentation, declaration, marking and use information.** · Priority: Blocking release
   Object / version: IV-240 Control Unit · IV-240 · CFG-B2 | Evidence: EMC evidence package | Owner: Alvena Engineering / Quality Assurance | Timing: Before release
   Closure criterion: Dated closure review with reference, object/configuration binding and assigned owner.
2. Verification required **Verify and correct evidence for the exact release configuration: Evidence does not match the release configuration.** · Priority: Blocking release
   Object / version: IV-240 Control Unit · IV-240 · CFG-B2 | Evidence: LVD safety objectives and supporting evidence | Owner: Alvena Engineering / Quality Assurance | Timing: Before release
   Closure criterion: Dated closure review with reference, object/configuration binding and assigned owner.

3. Verification required **Document all intended configurations, operating modes and electromagnetic environment in the EMC assessment.** · Priority: Close before release

   Object / version: IV-240 Control Unit · IV-240 · CFG-B2 | Evidence: EMC assessment basis | Owner: Alvena Engineering / Quality Assurance | Timing: Before release

   Closure criterion: Determine whether already documented EMC evidence covers the outstanding assessment basis; record source/configuration links and decision.

Key findings

Subject / requirement	Status	Basis
IV-240 Control Unit · Directive 2014/30/EU	Active	Case-supplied route; source acceptance pending.
IV-240 Control Unit · Directive 2014/35/EU	Active	Case-supplied route; source acceptance pending.

Status of this sample report

SYNTHETIC SAMPLE / NOT OFFICIALLY ISSUED. All companies, products and evidence are fictional. The all-zero RA1-format identifier at the end is a non-issued renderer placeholder, not a report issued by a host, provenance record or legal-source attestation. The legal routes and evidence have not been accepted by a competent source authority.

Full case and configuration profile

Attribute	Customer-reported value / baseline
Assessment date/time	2026-10-30T09:20:00+01:00
Source snapshot (per product assessment)	2026-10-30
Product	IV-240 Control Unit
Configuration	CFG-B2
Hardware revision	HW-B
Software	2.4
Firmware	2.4.1
Intended use	Control of industrial test and automation processes in commercial facilities
Manufacturer (customer-reported)	Alvena Prüftechnik GmbH
Target markets	DE, AT
Planned market event (customer-reported)	2026-12-16
Lifecycle	New release

Regulatory routes and assessment basis

Object	Regulatory area	Status	Reason
IV-240 Control Unit	Directive 2014/30/EU	Active	Case-supplied route; source acceptance pending.
IV-240 Control Unit	Directive 2014/35/EU	Active	Case-supplied route; source acceptance pending.

Evidence – required-item scope and customer-reported actual

Object / required item	Actual (customer-reported)	Effective release assessment
IV-240 Control Unit · IV-240 · CFG-B2 · Directive 2014/30/EU · EMC market-release evidence package	Customer-reported: Confirmed missing · Submitted revision: CFG-B2 · Reference: EMC-PKG-024-B2	Confirmed missing
IV-240 Control Unit · IV-240 · CFG-B2 · Directive 2014/30/EU · EMC assessment basis	Customer-reported: Partial · Submitted revision: CFG-B2 · Reference: EMC-MATRIX-024-B2	Partial
IV-240 Control Unit · IV-240 · CFG-B2 · Directive 2014/35/EU · LVD safety objectives and supporting evidence	Customer-reported: Complete · Submitted revision: CFG-A1 · Reference: SAFETY-SV-A1	Invalid for release configuration

Blockers, open points and external checks

Release blockers:

- IV-240 Control Unit · EMC market-release evidence package · Required evidence confirmed missing
- IV-240 Control Unit · LVD safety objectives and supporting evidence · Evidence does not match the release configuration

Open facts:

- IV-240 Control Unit · The legal-source and route baseline needed for this object, configuration and release event is not yet sufficiently qualified; resolve the specific outstanding basis before relying on the release assessment.
- IV-240 Control Unit · The legal-source and route baseline needed for this object, configuration and release event is not yet sufficiently qualified; resolve the specific outstanding basis before relying on the release assessment.

Reopen upon change

- Hardware/BOM/configuration/accessory baseline changes
- Software or firmware version changes
- Intended use or user group changes
- Manufacturer/importer/brand/responsible-person setup changes
- Target Member State or required language changes
- Release timing crosses a legal transition/currentness boundary
- Relevant dynamic authority/catalogue/external-body state changes

- Reassessment trigger confirmed for the relevant regulatory area

Scope and limitations

SYNTHETIC SAMPLE / NOT OFFICIALLY ISSUED. All companies, products and evidence are fictional. The all-zero RA1-format identifier at the end is a non-issued renderer placeholder, not a report issued by a host, provenance record or legal-source attestation. The legal routes and evidence have not been accepted by a competent source authority.

This assessment evaluates release readiness within the supplied and qualified regulatory route basis; it does not determine initial legal applicability.

Dynamic, national and external-body states are considered resolved only with documented current sources.

Document contents are not substantively verified automatically.

The listed required-item scope derives from the stated route profile but is not independently confirmed here as a statutory duty. Current evidence status is customer-reported.

Legal sources and reference status

Source date: 2026-10-30

Report reference NOT ISSUED