APPROVAL

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PURPOSE

This Quality Plan defines proportionate controls for the development, manufacture, release, distribution and ongoing monitoring of ASPIVIX non-medical products to ensure their safety, conformity with applicable requirements and performance for their intended purpose.

SCOPE

This Quality Plan applies to ASPIVIX non-medical products subject to applicable European Union and United States product safety requirements, including Regulation (EU) 2023/988 (GPSR) and relevant US legislation, as determined in the product-specific regulatory pathway. It covers products supplied commercially or free of charge, including demonstration and training products that are placed on the market, intended for use by both professionals and consumers.

These products are managed within the ISO 13485 ASPIVIX Quality Management System, in accordance with the general principles of the Quality Manual and the applicable sections of the procedures referenced herein.

RESPONSIBILITIES

Responsible for implementing and maintaining this Quality Plan is the RAQM. Additional responsibilities are as defined in the applicable SOPs referenced in this plan.

DOCUMENT HISTORY

Description of Changes	Version
Initial version	A

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1 Acronyms

B2B	Business to Business
CAPA	Corrective and Preventive Actions
CE	Conformité Européenne
CPSA	Consumer Product Safety Act (Law)
CPSC	Consumer Product Safety Commission (Authority)
DHF	Design History File
EU	European Union
FDA	Federal Drug Administration
GPSR	General Product Safety Regulation
GSPR	General Safety and Performance Requirments
ISO	International Standard Organization
MDR	Medical Device Regulation
N/A	Nota Applicable
NB	Notified Body
NC	Non Conformity
US	United States of America
PMCF	Post-Market Clinical Follow-up
PMS	Post Market Surveillance
RAQM	Regulatory Affairs and Quality Assurance
PRRC	Person Responsible for regulatory compliance
QA	Quality Assurance
QMS	Quality Management System
RHOS	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMF	Risk Management File
SOP	Standard Operator Procedure
USC	United States Code

2 QUALITY PLAN DESCRIPTION

This Quality Plan identifies the existing QMS procedures and sections applicable to non-medical products, together with the adaptations needed to address their intended use, risks and applicable EU and US requirements. The matrix in section 2.9 provides the corresponding references.

2.1 REGULATORY PATHWAY AND MARKET ACCESS

Following marketing and development teams' information, and before development, RAQM document the regulatory pathway, linked to the "Regulatory Product Requirements & Pathway" as described in SOP-200 §2.1.1. It shall identify the applicable regulations and standards, intended purpose, users, use environments, claims, markets, channels and economic operators, and justify the non-medical status.

EU: RAQM assesses the scope of Articles 2–3 of Regulation (EU) 2023/988 (GPSR), including reasonably foreseeable consumer use. "Professional use only" is not, by itself, an exclusion.

US: RAQM separately assesses the CPSA definition of consumer product, 15 USC 2052(a)(5), exclusions and specific CPSC rules. B2B sales alone do not exclude CPSC jurisdiction. The regulatory pathway shall also identify any applicable chemical, state, import and packaging requirements; other markets require a dedicated assessment.

2.2 DEVELOPMENT

The development must be executed according to relevant steps specified in SOP-200. The plan shall define activities, responsibilities, acceptance criteria and reviews. For these products, the five reviews may be combined, with an approved rationale in the plan, while retaining evidence of the required review content. The need of an independent reviewer of the activity reviewed is discretional based on project complexity. At a minimum, input approval and final approval before commercialization shall be documented.

A single, proportionate DHF shall also serve to document due diligence to ensure safety and performance. It shall contain or reference as a minimum:

- Marketing requirements
- Design and development plan
- Regulatory pathway
- User requirements specifications
- Design input requirements
- Design description
- Intended use;
- Risk analysis
- Labeling
    - IFU, as appropriate
    - Labels with minimum: product description, product identification, Lot and safety information, manufacturer details; importer and EU operator details where applicable
- Design V&V protocols/reports
- Design transfer and process validation
- Drawings, specifications, bill of materials and materials;
- GPSR checklist from the Regulation (EU) 2023/988 (GPSR) with justified applicability and references to evidence;

Concerning product verification and validation, a protocol defining measurable requirements, sample selection and justification, test methods and conditions, acceptance criteria and deviation handling should be approved.

Verification should cover dimensions, assembly and claimed functional performance. Validation should confirm suitability for demonstration with representative users under representative conditions, using production-representative units. Service life/use cycles, cleaning where intended, packaging and transport should be included as applicable. Results, anomalies and conclusions should be documented, with traceability between inputs, risks and tests.

Medical sections of document templates shall be marked N/A with a rationale. Applying this SOP does not, by itself, require clinical evaluation, PMCF, MDR GSPR, UDI identification, medical device registrations or CE marking. Where other legislation requires them, the regulatory pathway shall define their application. Template adaptations are allowed to comply with this approach and justified as appropriate.

Changes to design shall be managed under SOP-303. The impact assessment shall determine regulatory pathway/risk updates, verification, revalidation, stock disposition and implementation date. Medical device-specific FDA/NB assessments do not apply automatically;

2.3 RISK MANAGEMENT

Before release, hazards, exposure, severity and probability, acceptance criteria, control measures and evidence of their effectiveness shall be identified. Intended use and reasonably foreseeable misuse, materials and process residues, breakage or detachment of parts, sharp edges, cleaning, deterioration, storage and transport, assessed. Interactions with the product being demonstrated and the possibility of mistaking the model for a product suitable for clinical use must be addressed as appropriate (i.e. the case of training models replicating an actual medical device).
A single consolidated risk assessment may replace multiple FMEA/usability documents if it contains all relevant elements. Any detectability scores or separate analyses shall be defined in the plan according to risk. The order of priority remains:

- safety by design,
- protective measures,
- information.

A training benefit does not justify a risk incompatible with safety requirements. Material and biocompatibility studies shall be selected according to actual exposure, without automatically applying the medical device testing package, and literature searches on the state of the art could be evaluated for the demonstration of conformity as appropriate.

2.4 MANUFACTURING, IDENTIFICATION AND RELEASE

Manufacturing shall be conducted with validated process and controls to ensure product compliance to performance and safety requirements, according to the prescriptions of SOP-202 and 206.

Each production run shall be assigned a batch/LOT number in accordance with SOP-203. The batch record shall link product reference and revision, quantities, materials and supplier batches, dates, operators, relevant equipment/configurations, parameters, inspection results, scrap and nonconformities. Recipients, quantities and shipped batches shall be recorded, including free supplies and demonstration products. Marketing a product as a demonstration model does not permit release controls to be bypassed.

For each batch, RAQM, or a formally authorized qualified delegate, shall verify complete records, compliance with final acceptance criteria, correct identification, labeling and packaging, closure of relevant nonconformities and continued validity of manufacturing conditions. The decision, date, signature and quantity released shall be recorded. UDI checks are not required unless specified for that product. Release is a QMS responsibility, not an MDR PRRC obligation for the non-medical product. No concession may waive legal safety requirements.

2.5 DISTRIBUTION

Approve packaging and storage/shipping conditions and verify the authorized market before each shipment.

Before the first EU shipment subject to GPSR, RAQM shall identify the responsible economic operator established in the Union under Article 16 and formalize duties, access to the technical file and reporting coordination. An existing appointment for medical devices does not automatically cover these products. Operations shall verify consistency between labeling and the distribution flow.

Before US importation, RAQM shall document whether the product is subject to CPSC rules requiring certification. If so, define testing, the General Certificate of Conformity or other relevant certification, importer responsibilities and eFiling under 16 CFR Part 1110, including applicable deadlines/exceptions. eFiling is required from July 8, 2026 for most regulated imports subject to certification; it is not a blanket requirement for every non-medical product

2.6 COMPLAINTS, MONITORING AND REVIEW

Apply SOP-103, SOP-106 and SOP-104 using classifications appropriate to the non-medical product. Any potential safety issue shall be escalated immediately to RAQM or the designated deputy. Where necessary, the batch and shipments must be blocked, and evidence preserved. Assessment of products already distributed must be assessed and safety communications promptly initiated.

At least annually, AQ and CTO shall review production data, complaints, returns, nonconformities, suppliers, relevant safety information, regulatory changes, risks and validations. Record conclusions and actions in a proportionate review under SOP-107; bring the review forward when a signal arises. Clinical PMS/PMCF is not required; proportionate active monitoring remains applicable, including inspections or sample testing where justified by risk.

2.7 EU AND US REPORTING

EU: where GPSR applies: if the manufacturer considers or has reason to believe that a product placed on the market is dangerous, RAQM shall immediately initiate corrective measures, consumer information and notification to the authorities of the affected Member States through the Safety Business Gateway under Article 9(8). For accidents under Article 20, including death or serious adverse effects on health and safety, ensure notification without undue delay to the authorities of the country where the accident occurred. Coordinate the importer and responsible EU operator; record facts, dates, assessment, submissions and updates. Do not wait for the investigation to be completed before fulfilling obligations that have already arisen.

US: where subject to CPSC: RAQM and the US operator shall immediately assess the reporting conditions under CPSA §15(b), 15 USC 2064(b), and 16 CFR Part 1115: relevant noncompliance, defects that could create a substantial product hazard, or an unreasonable risk of serious injury/death. Reporting shall occur within 24 hours of obtaining information reasonably supporting these conclusions; actual harm need not have occurred. Any

preliminary investigation allowed in cases of genuine uncertainty is not an automatic waiting period. The regulatory pathway shall also identify any other applicable reporting obligations.

Where GPSR/CPSC does not apply, RAQM shall promptly identify the relevant authorities and obligations from the regulatory pathway. The medical device vigilance deadlines and thresholds in SOP-108 do not replace those in this section.

RAQM shall coordinate the decision, affected batches and recipients, stock blocking, communications, recovery/remedy, quantity reconciliation and effectiveness checks. Reuse the operational part of SOP-108 §3.4, adapting content and recipients to the applicable framework. For GPSR, comply with Articles 35–37: direct contact where possible, a compliant recall notice and effective, free and timely remedies. Coordinate US actions with CPSC where relevant. Closure requires evidence of effectiveness and assessment of the need for CAPA.

2.8 RETENTION AND AVAILABILITY

As an internal rule, retain the DHF and production/distribution records for at least 10 years after the product was last placed on the market, unless the regulatory pathway defines longer periods. For GPSR: Article 9(3), technical documentation for 10 years; Article 15(4), safety information for 10 years and supply-chain information for 6 years, subject to the terms specified therein. Separate complaint personal data: retain only as necessary and no longer than 5 years after entry in the GPSR register, Article 9(13); anonymize technical data retained for longer. Ensure controlled access, availability to authorities and backups under SOP-300

2.9 APPLICABLE PROCEDURE MATRIX

Below the applicable procedure matrix which highlights the link between sections of existing procedures while the adaptations are described across the section 1.1 to 1.8 of this SOP. the associated work instructions are covered by the reference to the SOP.

Requirement	Applicable procedure	Applicable sections
Regulatory status and applicability by market. EU: GPSR Arts. 2–3; USA: 15 USC 2052(a)(5).	SOP-200; SOP-209	200: §2.1.1, §2.1.2.1 209: §3
Internal product safety processes and responsibilities. EU: GPSR Art. 14. USA: internal control supporting applicable obligations.	SOP-209	§§1–2, §8, §9
Development plan and proportionate reviews. Internal control; supports GPSR Art. 9(2).	SOP-200; SOP-209	200: §1.2, §2.1.1 209: §4.1
DHF, GPSR checklist and US evidence. EU: Art. 9(2)–(3); USA: specific requirements identified in the regulatory pathway	SOP-200; SOP-300; SOP-209	200: §2.6 300: §§4.1–4.5, §4.9 209: §4.1, §7.4
Inputs, outputs and claimed performance. EU: GPSR Arts. 5–6; performance as an internal requirement.	SOP-200; SOP-209	200: §2.1.2, §2.2 209: §§4.1–4.3
Risk analysis, reduction and review. EU: Arts. 5–6, 9(2). USA: evidence supporting applicable rules and CPSA §15.	SOP-302; SOP-209	302: §3.1, §3.2, §3.3.1–3.3.2, §3.3.4–3.3.5, §§3.4–3.7 209: §4.2, §7.1
Verification, functional validation and representative use. EU: GPSR Arts. 6, 9(2); additional testing according to regulatory pathway	SOP-200; SOP-206; SOP-209	200: §2.3.1 206: §§2.2–2.3 209: §4.3
Transfer and manufacturing documentation. EU: GPSR Art. 9(4); internal US control.	SOP-200; SOP-206; SOP-209	200: §2.3.2 206: §2.4 209: §4.4, §5.1
Changes and their impact on safety and conformity. EU: GPSR Art. 9(4); USA: according to regulatory pathway	SOP-303; SOP-209	303: §2.1, §2.2 209: §4.4

Requirement	Applicable procedure	Applicable sections
Suppliers and purchasing against approved specifications. Internal controls supporting safety and conformity.	SOP-201; SOP-305	201: §2.1 305: §§2.1–2.7
Requirement	Applicable procedure	Applicable sections
Incoming inspections and material status. Internal control supporting GPSR Art. 9(4).	SOP-201; SOP-202; SOP-203	201: §2.1.4–2.1.7 202: §2.4 203: §1.4
Internal manufacturing, instructions and records. EU: GPSR Art. 9(4); quality and repeatability as internal controls.	SOP-202; SOP-209	202: §§2.1–2.4 209: §§5.1–5.2
Process validation and revalidation. Internal control based on risk and verifiability.	SOP-206; SOP-209	206: §2.5 (excluding §2.5.2), §2.6, §2.8 209: §5.1, §7.1
Equipment, environment, maintenance and calibration. Internal control.	SOP-301; SOP-209	301: §§1.1–1.2, §2.2 209: §5.1
Product/batch identification and supply chain. EU: GPSR Arts. 9(5), 15(3)–(4). Batch/material linkage: internal implementation choice.	SOP-203; SOP-209	203: §§1.1–1.4 209: §5.2, §7.4
Initial approval and market authorization. Internal control; legal prerequisites according to regulatory pathway.	SOP-200; SOP-209	200: §2.3 209: §3, §5.3
Final inspection and documented batch release. EU: supports GPSR Arts. 5, 9(4); signature/record as an internal control.	SOP-202; SOP-106; SOP-209	202: §2.5 106: §3 209: §5.3
Labeling and instructions. EU: GPSR Arts. 9(5)–(7), 11(3), 16(3), 21. USA: obligations identified in the regulatory pathway, including FHSA where applicable.	SOP-306; SOP-209	306: §§2.1–2.2, §2.4.1, §§2.5–2.6 (document workflow only) 209: §6
EU operator, importer and distributors. EU: GPSR Arts. 11–12, 16. USA: roles/importation according to regulatory pathway.	SOP-205; SOP-209	205: §2 209: §3, §9
Marketing claims and online offers. EU: GPSR Art. 19; USA: specific regulatory pathway requirements.	SOP-205; SOP-209	205: §§1.2–1.6, §2.1 209: §6
Requirement	Applicable procedure	Applicable sections
Packaging, preservation and traceable shipping. EU: GPSR Art. 6 and Arts. 11–12 where relevant; internal controls.	SOP-202; SOP-203; SOP-207; SOP-209	202: §§2.6–2.7 203: §§1.3–1.4 207: §§1.1–1.2 209: §§5.2–6
US certification/testing and eFiling only where required. CPSA §14, 15 USC 2063; 16 CFR Part 1110.	SOP-209	§3, §9
Complaint receipt, recording and investigation. EU: GPSR Art. 9(11)–(12). USA: supports CPSA §15 assessment.	SOP-103; SOP-209	103: §§3.1–3.3, §§3.5–3.7 209: §7.1, §7.4
Safety monitoring and updating. EU: GPSR Arts. 9, 16(2) where applicable. USA: internal control and assessment of information received.	SOP-107; SOP-302; SOP-209	107: §§2.1–2.6 302: §§3.6–3.7 209: §7.1

Requirement	Applicable procedure	Applicable sections
Non-medical product reporting. EU: GPSR Arts. 9(8), 20. USA: CPSA §15(b), 16 CFR Part 1115.	SOP-209	§7.2
Withdrawals, recalls and remedies. EU: GPSR Arts. 35–37. USA: CPSA §15, actions coordinated with CPSC where relevant.	SOP-108; SOP-209	108: §3.4.1 (recall operations), §§3.4.3–3.4.4 209: §7.3
Nonconformities and CAPA, including supplier actions. Internal controls; support GPSR Art. 9(8).	SOP-106; SOP-104; SOP-209	106: §§2–4 104: §2 209: §5.3, §§7.1–7.3
Documents, training and retention. EU: GPSR Arts. 9(3), 9(13), 15(4). USA: specific periods from regulatory pathway.	SOP-300; SOP-209	300: §§1–2, §§4.1–4.11 209: §7.4, §9
Audits and process effectiveness review. Internal QMS control.	SOP-304; SOP-107; SOP-209	304: §§3.1–3.4 107: §2.4 209: §7.1, §9

3 REFERENCES

Regulation (EU) 2023/988 on general product safety: https://eur-lex.europa.eu/eli/reg/2023/988/oj

Commission Notices C/2025/6233 (GPSR application) and C/2025/6238 (Safety Business Gateway): https://eur-lex.europa.eu/eli/C/2025/6233/oj and https://eur-lex.europa.eu/eli/C/2025/6238/oj

CPSA: 15 USC §§2052, 2063, 2064; 16 CFR Parts 1110 and 1115: https://uscode.house.gov/ and https://www.ecfr.gov/current/title-16/chapter-II

CPSC: certification and eFiling: https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/General-Certificate-of-Conformity and https://www.cpsc.gov/eFiling

Additional areas to assess: REACH (EC) 1907/2006, Article 33 and Annex XVII; FHSA, 15 USC 1261–1278 and 16 CFR Part 1500; California Proposition 65, HSC §25249.6, according to materials, exposure and market.

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Tax ID: CHE-347.247.288 TVA

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Printed on 2026-10-22 - 08:49:59 UTC

Document Details

Created by: Mauro Rinaldi
Created on: 10/16/2026 14:29:35 (UTC)
Creation IP Address: 213.55.240.13
Signers: 3

Document ID: 1139
Signature:
04cb324ed180eb90ec69427b4086bde219bd6897404096021782b3cce631f40a

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		Signature: d5f476695398741dbde7f41b672dbd284c4988ac30024993ad81ff644366bb91		

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Aspivix SA, Mauro Rinaldi mauro.rinaldi@aspivix.com	10/22/2026 08:49:56	After Signature	47.3779000, 8.5236000 View	213.55.240.13