FOR-DND-011

Performance Evaluation Plan (PEP) <Name of the Device>

Template revision	Version	Brief description or reason for the revision	Approved by <@name>, <function>, on yyyy/mm/dd
	x		

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Status of the record	Version history of the record
State: Review	**Change History**

Approvals	Reviewer	Status	Date	Comment
Approval		PENDING		

Page Version	Date	Comment
Current Version (v. x)	<Date>	QA Manager

Signatures required for the record

Meaning (Prepared by, Reviewed by, Approved by, Read and understood)	Function of signatories	Name of signatories

This document defines the planned strategy, scope, and methodology for the performance evaluation of the device in accordance with IVDR requirements.

It does not contain conclusions regarding performance, safety, or regulatory conformity, which are documented separately in the Performance Evaluation Report.

1. Introduction

- Device Name:
- Intended Purpose:
- Intended User and Use Environment:
- Device Type and Classification (per IVDR):
- Reference to Applicable GSPRs:
- Link to the overall Clinical Evaluation Strategy and Technical Documentation

The intended purpose described above is defined in the approved design inputs documented in FOR-DND-003 design inputs <Name of the Device>.

2. Objectives of the Performance Evaluation

- To demonstrate:
  - **Scientific Validity**
  - **Analytical Performance**
  - **Clinical Performance**
- To define the methods that will be used to generate, collect, appraise, and analyse performance data in order to support the assessment of scientific validity, analytical performance, and clinical performance of the device.

3. Scope of the Evaluation

- Type of Evaluation: [Initial / Update]
- Version(s) of the Device Covered:
- Markets Intended (EU / other regions if applicable)

4. Overview of Performance Evaluation Elements

The performance evaluation elements described in this section are based on the finalized design outputs documented in FOR-DND-004 Design Outputs & Traceability Matrix <Name of the Device>.

Element	Description
Scientific Validity	Describe the analyte/marker and clinical association
Analytical Performance	Testing design, methods, parameters (e.g., LoD, precision, interference)
Clinical Performance	Study or literature plan to demonstrate diagnostic accuracy (PPA/NPA, etc.)

5. Data Sources and Collection Methods

5.1 Scientific Validity

- Literature search strategy
- Inclusion/exclusion criteria
- Databases: [e.g., PubMed, Embase, CLSI]

5.2 Analytical Performance

- Internal and/or external laboratory studies
- Summary of planned protocols and methods

5.3 Clinical Performance

- Clinical study plans (if applicable)
- Literature review for clinical data (if study not required)
- Post-market clinical data (if applicable)

6. Methodology

- Criteria for data selection and critical appraisal
- Statistical methods for performance analysis
- Evaluation and acceptance criteria

7. Responsibilities

Function	Responsibilities
Regulatory Affairs	Plan oversight, ensure regulatory alignment
Clinical Affairs	Data collection, literature review
R&D	Design and execute analytical studies
Quality Assurance	Document control, compliance verification

The complete template is included in ReadySet

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