SOP-DND-012

# Performance Evaluation - IVDR

| Document status | Version history |
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| State: Review | **Change History** |

| Approvals | Reviewer | Status | Date | Comment |
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| Approval | | PENDING | | |

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

## Signatures required

| Signature required / meaning (Prepared by, Reviewed by, Approved by, Read and understood) | Function of signatories | Name of signatories |
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## References

**Regulation (EU) 2017/746 (IVDR) – Article 56 Performance Evaluation**
Article 56 requires manufacturers to establish, document, maintain, and continuously update a performance evaluation demonstrating the scientific validity, analytical performance, and clinical performance of the IVD device throughout its lifecycle.

**Regulation (EU) 2017/746 (IVDR) – Annex XIII Performance Evaluation, Performance Studies and Post-Market Performance Follow-up**
Annex XIII defines the methodology, planning, conduct, documentation, review, and continuous updating of the performance evaluation process, including the demonstration of scientific validity, analytical performance, and clinical performance.

## 1. Summary

This procedure defines how performance evaluation activities are planned, performed, documented, and maintained to demonstrate conformity of In Vitro Diagnostic (IVD) devices with IVDR requirements.

Performance evaluation is a continuous process initiated during development and actively maintained throughout the product lifecycle.

## 2. Scope

This procedure applies to all **In Vitro Diagnostic (IVD) devices** developed under Regulation (EU) 2017/746 (IVDR), including devices for professional use and self-testing.

It covers performance evaluation activities performed during:

- design and development,
- conformity assessment,

- post-market phases.

## 3. Inputs

Performance evaluation activities are initiated and maintained based on, as applicable:

- Device description and intended purpose
- Claims and performance claims
- Risk management documentation
- Scientific, analytical, and clinical performance data
- Post-market surveillance and PMPF data

Design and development activities are planned in accordance with SOP-DND-001 Product Realization Planning.

Design changes impacting performance evaluation are managed in accordance with SOP-DND-009 Design and Development changes.

Risk management activities are performed in accordance with the organization's risk management process.

## 4. Process Description

### 4.1 Performance Evaluation Planning

Performance evaluation activities are planned through a FOR-DND-011 Performance Evaluation Plan (PEP) `<Name of the Device>` v1 that defines, as applicable:

- intended purpose and performance claims,
- applicable IVDR requirements,
- performance evaluation strategy,
- methods for generating and appraising performance data,
- procedures for updating the performance evaluation.

The PEP is established during development and maintained throughout the product lifecycle.

### 4.2 Performance Evaluation Team

Performance evaluation is conducted by a suitably qualified individual or team based on:

- IVD technology and intended use,
- complexity and risk profile of the device,
- required scientific, analytical, and clinical expertise.

Evaluator qualifications and experience are documented.
Declarations of interest are obtained and retained.

### 4.3 Scientific Validity

Scientific validity is established by demonstrating the association between the analyte and the clinical condition or physiological state.

Scientific validity data may be based on, as applicable:

- scientific literature,
- consensus standards or guidelines,
- expert opinions.

The relevance and limitations of scientific validity data are documented.

**The complete procedure is included in ReadySet**

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