Performance Evaluation Plan (IVDD)

The Performance Evaluation Plan lays out the resources and methods for the evaluation of the performance of the IVD.

> There's a separate standard available for that: EN 13612:2002. It's very short and doesn't contain a whole lot of information. You can generally understand what it's about when you look at the mapping of requirements to document sections table below. Additionally, there are three IMDRF guidance documents which are more relevant for the Performance Evaluation Report:
>
> - [GHTF/SG5/N6:2012][imdrf-1]
> - [GHTF/SG5/N7:2012][imdrf-2]
> - [GHTF/SG5/N8:2012][imdrf-3]

Product

- Name: *<product name>*
- Version: *<product version>*
- Basic UDI-DI: *<insert UDI-DI, if/when available>*

Mapping of Requirements to Document Sections

EN 13612:2002 Section	Document	Section
3.1 Responsibilities and Resources	Performance Evaluation Plan (this one)	5
3.2 Documentation	Performance Evaluation Plan (this one)	(all)
3.3 Final Assessment and Review	Performance Evaluation Report	
4.1 Preconditions	Performance Evaluation Report	
4.2 Evaluation Plan	Performance Evaluation Plan (this one)	6, 7
4.3 Sites and Resources	Performance Evaluation Plan (this one)	5
4.4 Basic Design Information	Performance Evaluation Plan (this one)	7.3
4.5 Experimental Design	Performance Evaluation Plan (this one)	7.4
4.6 Performance Study Records	Performance Evaluation Plan (this one)	7.5
4.7 Observations and Unexpected Outcomes	Performance Evaluation Plan (this one)	7.6

EN 13612:2002 Section	Document	Section
4.8 Evaluation Report	Performance Evaluation Report	
5. Modifications During the Performance Evaluation Study	Performance Evaluation Plan (this one)	8
6. Re-evaluation	Performance Evaluation Plan (this one)	8
7. Protection and Safety of Probands	Performance Evaluation Plan (this one)	9

1. List of Abbreviations

Abbreviation	Explanation
IVD MD	In-vitro diagnostic medical device

2. Product

- Name: *<product name>*
- Version: *<product version>*
- Basic UDI-DI: *<insert UDI-DI, if/when available>*
- UMDNS-Code:
- GMDN-Code:

3. Relevant Documents

- SOP Performance Evaluation
- Performance Evaluation Plan

4. Intended Use

Copy-paste the intended use of your device here.

5. Responsibilities and Resources

5.1 Personnel

These five tasks are explicitly specified in EN 13612, so you should assign them to someone. Feel free to add further tasks if you have any. Of course, one person can take care of multiple tasks.

Task	Personnel
Coordinator with overall responsibility	John Doe
Assess the validity of test results and data already available	John Doe Jr.

Task	Personnel
Specify performance claims which shall be further examined or confirmed	John Doe Sr.
Specify and document the evaluation plan and the test procedures	John Doe II
Prepare the evaluation report	Albert Einstein

5.2 Resources

Describe other resources which you need for performance evaluation, e.g. software and hardware, physical locations.

6. Performance Claims of IVD MD

For each performance claim, assess whether it's applicable to your IVD, i.e. can you measure that specific parameter, based on your device output? Then, add an explanation about what those parameters actually mean in the context of your device.

An example could be that you're manufacturing an HIV test. Then, analytical sensitivity is applicable, and your explanation would be something like "proportion of HIV-positive patients who have positive test results".

Performance Claim	Applicable?	Explanation
Analytical Sensitivity	yes/no	
Diagnostic Sensitivity		
Analytical Specificity		
Diagnostic Specificity		
Accuracy		
Repeatability		
Reproducibility		

7. Evaluation Procedure

7.1 List of Laboratories and Other Institutions Taking Part in Study

List the labs which take part in your study. If your product is for self-testing, list the "lay persons" who are your study participants.

7.2 Time Table

Create some sort of timeline when to do what.

Date	Activity
	Plan Performance Evaluation
	Conduct Performance Evaluation
	Write Performance Evaluation Report

7.3 Briefing of Investigators

If your investigators (the people who conduct the study) aren't familiar with your device, describe how you'll provide them with the necessary information beforehand.

7.4 Software Validation

The device is stand-alone software and will be validated in accordance with IEC 62366-1:2015, see SOP Integrated Software Development.

7.5 Performance Study Records

Describe how and where records of your performance study will be saved. Those could be files which contain your analysis data, or even the input data (i.e., test set) which you used for it.

7.6 Observations and Unexpected Outcomes

Describe what you'll do when an unexpected outcome happens. Might not apply to stand-alone software.

8. Re-Evaluation

Specify under which conditions your performance evaluation will be repeated. That's mainly the case when you change your device.

9. Protection and Safety of Probands

Describe how you ensure the safety of your probands. Probably not be applicable to software in most cases.

10. Dates and Signatures

Date and sign the plan. If your document management system supports it, you can digitally sign by typing e.g. your initials in the "Signature" field. Otherwise, you can still sign it the old-school way (print it and sign the sheet of paper, ugh).

Activity	Name	Signature
Creation		
Review		
Approval		
