Disclaimer: This example is only one way of documenting and does not automatically guarantee the completeness of all necessary information that the manufacturer must provide.

Performance Evaluation Report

(acc. EU 2017/746 (IVDR) Annex XIII Part A 1.3.2.)

Manufacturer:

Product name:

Product Catalog No.:

Basic-UDI-DI:

Date/ Version:

Signature
(function)

Content

1. Product information

Product name:	
Product Catalog No.:	
Basic UDI DI:	
Risk class:	
Intended Use:	

2. Method description

Description of the test principle of the device.

3. Assessment of Performance Evaluation

3.1 Details about Performance Evaluation

Reference to internal standard operating procedures describing how the manufacturer assess the performance evaluation.
The Performance Evaluation of the IVD medical device means an assessment of the scientific validity report, analytical performance report and clinical performance report to demonstrate the clinical evidence for the device and includes the following detailed assessment steps.

3.2 Justification for the approach taken to gather the clinical evidence

Reference to the clinical performance report.

3.3 Details about the Literature Search

Reference to the clinical performance report.

3.3.1 Claims about performance and safety

Results of risk assessment and necessary claims for the instruction for use.

3.3.2 Nature and extent of the assessed data

Explanation and overview about all assessed data.

3.3.3 Acceptance of clinical evidence against the state of the art in medicine

Statement with rationale.

3.3.4 New results derived from PMPF report

Results out of the post market performance.

4. Conclusion

Conclusion about the main performance results.

5. Document history