

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.

Scientific Validity Report

(acc. EU 2017/746 (IVDR) Annex XIII Part A 1.2.1)

Manufacturer:

Product name:

Product Catalog No.:

Basic-UDI-DI:

Date/ Version:

Date/ Signature
(function)

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1. Product information

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

2. Method description

Description of the test principle of the device.

3. Assessment of Scientific Validity

Reference to internal standard operating procedures describing how the manufacturer assess the scientific validity..

3.1 Details about Scientific Validity

3.2 Used sources

- information on the scientific validity of devices measuring the same analyte or marker;
- scientific (peer-reviewed) literature;
- consensus expert opinions/positions from relevant professional associations;
- results from proof of concept studies;
- results from clinical performance studies.

3.3 Details about the Literature Search

Scope of the literature search	
Date of search	
Name of person(s) undertaking the literature search	
Period covered by search	
Literature sources used to identify data	

Database search details	
Selection criteria used to choose articles	
Data selection process	

4. Conclusion

5. Attachment

Literature

6. Document history