The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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Considerations for conformity assessments done by (IVD) Notified Bodies in the case of down classification of SARS-CoV-2 tests.

1. Background:

The disease COVID-19 caused by the SARS CoV-2 virus was declared a pandemic in March 2020 by the World Health Organization. The severity of the clinical forms and the speed of propagation of the virus in the population led the MDCG to consider SARS-CoV-2 as an agent causing life-threatening disease with a high risk of propagation, notably with regards to the definition of 'life threatening' and considerations around 'high risk of propagation' provided in the IVD classification guidance MDCG 2020-16. Therefore, in the context of classification of in vitro diagnostic medical devices (IVDs) according to Annex VIII of Regulation (EU) 2017/746, the MDCG included it as an example of infectious agents under Rule 1, 2nd indent in the MDCG 2020-16 guidance, so that IVDs that detect the presence or exposure to SARS-CoV-2 would generally be classified as class D. Since 2020, many tests with different designs have been placed on the EU market, such as direct detection tests (NAT, antigen) and indirect tests (intended for detection of antibodies, neutralizing or not). In July of 2024, the MDCG has requested a scientific advice from the expert panel on the various scientific questions related to SARS-CoV-2, as well as more generally on respiratory viruses, in the context of the classification rules in Regulation (EU) 2017/746. The expert panel has published their scientific advice(1) on SARS-CoV-2 on 29 January 2025. Which again resulted in an update of the document MDCG 2020-16, now rev.4, to reflect the change in classification for COVID tests (2).

As a result of the discussed scientific advice the IVD Expert Panel gave on SARS-CoV-2 / COVID tests (January 2025), the European Commission has asked the IVD Notified Bodies to create a list of considerations on how they would practically manage a down classification if this were to happen. This document is intended to come with a general approach that all IVD Notified Bodies can apply when transitioning this change.

2. Current CE Certification of SARS-CoV-2 test and impact of MDCG 2020-16 rev.4:

At the time of publication of MDCG 2020-16 Rev. 4, IVD's intended for determining, screening and diagnosing SARS CoV-2 are Class D per rule 1 of Annex VIII of the IVDR, irrespective of whether the device is intended for self-testing purpose or near patient purpose (highest classification rule applies). Some devices may have multiple intended purpose and analytes (multiplex). This means that SARS-COV-2 tests, originally, are covered by an EU Technical Documentation assessment certificate per Annex XII of the IVDR.

Per the publication of the scientific advice, and updated MDCG 2020-16 rev.4, the following has changed:

- Examples under rationale for rule 1, second indent does not mention SARS-CoV-2 anymore; SARS-CoV is however still mentioned as an example, under this rule.
- Rationale under rule 4a (devices for self-testing) has been updated to reflect self-testing devices for the detection of SARS-CoV-2 or antibodies against SARS-CoV-2 to be in class C, including revision of examples.
- Rationale under rule 6 has been updated to now reflect a general statement that in case of changes in the epidemiological context were to happen, classification rules 1 or 3 could become applicable and the class of the device revised; which applies to all devices and is not limited to SARS-CoV-2.
- Examples under rationale for rule 6; devices intended for the detection of SARS-CoV-2 and devices intended for the detection of antibodies against SARS-CoV-2 are now added as examples.

In summary, this means that:

1. SARS-COV-2 tests intended for professional use (by trained laboratory professionals) will change classification from Class D to Class B, per rule 6.*
2. SARS-COV-2 tests intended for self-testing will change from Class D to Class C per rule 4a.
3. SARS-COV-2 tests for near patient testing are classified on their own right, in line of that of other devices for professional use.
4. In case where SARS-COV-2 tests are intended to be used in both a professional as well as a self-test / near patient test; the highest classification will be applicable: Class C.
5. SARS-COV-2 tests that are part of a multiplex device: appropriate classification will need to be determined on a case-by-case basis, applying the principles under 1,2 and 3 above.

*There may be a scenarios where a SARS-COV-2 test is specially intended for donor screening; in this situation, rule 1 would still be applicable, placing the device under Class D.

3. Certification scenarios applicable:

It is expected that the manufacturer will update the technical documentation to reflect the change in classification and submit a **change notification** to the Notified Body to inform them in making the appropriate corrections. The Notified Body will then assess this request and make the necessary amendments in the certification application. In general, a total of four certification scenarios is expected to play out, after the publication of the MDCG 2020-16 rev. 4, including the appropriate course of action:

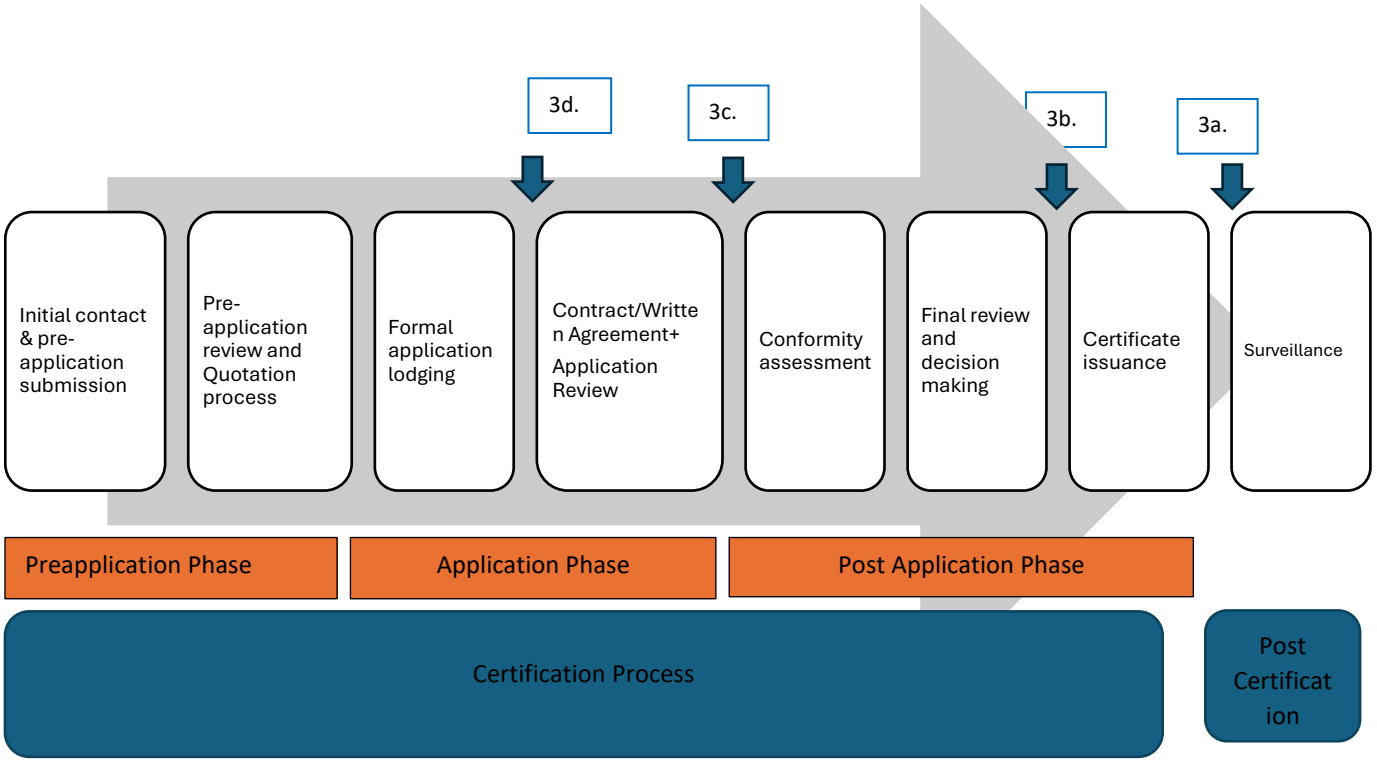
a. A **Class D EU Technical Documentation assessment certificate** has previously been **issued** for the SARS-COV-2 test.
   ➔ In **this particular scenario**, after receiving the relevant change notification from the manufacturer, the Notified Body will review and revise the certification structure, such as; remove the Class D certificate, issue of Class B or C certificate, change the scope, etc.

b. A **Class D application** of the manufacturer has **been submitted and accepted following review** by a Notified Body, and the technical documentation is **being reviewed and QMS audit process has been started**. This has not yet resulted in a Class D certificate decision / certificate yet.
   ➔ In **this particular scenario**, when a certification of a Class D device is ongoing the Notified Body will try to finalize the conformity assessment **per agreed schedule** and **before** the final review and certification decision step to apply the down-classification review. **Or** finalize the Class D certification process altogether on condition that the certificate will be revised **directly after review** change notification. What route is most appropriate, will be agreed between the manufacturer and the Notified Body to prevent delay to market for devices, on a case by case basis.

c. A **Class D application** has been **submitted and accepted** following review and the conformity assessment activities planned by a Notified Body, **however**, the technical documentation review and/or the audit process **has not been initiated yet**.
   ➔ In **this particular scenario**, the change notification review will be initiated instead, **before the technical documentation review and QMS audit starts**. The change notification would also lead to a review of updated technical documentation and QMS data (when needed). The documentation would, in its entirety, support the continuation of the certification process from this point on.

d. A Class D application has been submitted by a manufacturer to a Notified Body, but this has **not been reviewed and/or accepted** by the Notified Body, yet. No planning activities have been started.
   ➔ In **this particular scenario**, the Notified Body will **halt the review** of the application and request the manufacturer for a new/updated application. And start the process from there.

   See also below Infographic.



Re-classification, in general, is not a new phenomenon for Notified Bodies, for instance as a result of a classification dispute for instance. The following activities and related responsibilities need to be considered by Manufacturers and Notified Bodies in the case of a change in classification.

For clarity, this document is directed towards the down-classification of a SARS-CoV-2 assay, but the principles may also apply to other devices that are eligible for down-classification.

Table 1: Activities and responsible actors

Manufacturers Activity (QMS related)	**Scenario Applicable**	**NB process steps**
Gap analysis and impact assessment of the change	3a. 3b. 3c. 3d.	Application, Conformity Assessment, Surveillance
Update GSPR checklist (Annex I)	3a. 3b. 3c. 3d.	Application, Conformity Assessment, Surveillance
Update Technical Documentation (Annex II)	3a. 3b. 3c.	Application, Conformity Assessment, Surveillance
Update PMS documentation (Annex III)	3a. 3b. 3c.	Application, Conformity Assessment, Surveillance
Update Risk Management File	3a. 3b. 3c.	Application, Conformity Assessment, Surveillance
Remove/update Summary of Safety and Performance	3a. 3b. 3c.	Application, Conformity Assessment, Surveillance
Update Declaration of Conformity	3a. 3b. 3c. 3d.	Application, Conformity Assessment, Surveillance
Update Classification Justification Statement	3a. 3b. 3c. 3d.	Application, Documentation review, Surveillance
Notified Body Activity	**Scenario Applicable**	**NB process steps**
Determine impact on issued certificate, if applicable	3a. 3b.	Application, Planning
Determine impact on (earlier) reviewed application	3a. 3b. 3c.	Application, Planning
Determine impact on ongoing TD and/or TD surveillance schedule, sampling.	3a. 3b. 3c.	Application, Planning, Conformity Assessment
Determine impact on audit schedule	3a. 3b. 3c.	Application, Planning, Audit process
Update Surveillance (including Audit) Schedule, sampling	3a. 3b.	Application, Planning
Review updates to (part of) technical documentation	3a. 3b.	Conformity Assessment
Initiate Certification Decision process	3a. 3b.	Final review / Decision making
Stop Class D oversight (EURL / Alternative means)	3a. 3b.	Final review / Decision making
Change/Initiate certificates or applications	3a. 3b.	Final review / Decision making
Oversight in Surveillance phase per updated audit and technical documentation plan, sampling	3a. 3b.	Surveillance, Audit process

5. Operational Aspects:

As with all changes in regulations that impacts the regulatory status of a product, this will need to be reported by the manufacturer to the Notified Body. It is not expected that a manufacturer will need to start over a new application in all above mentioned scenarios; the manufacturer is required to submit a change notification to the Notified Body as the leading document that will consist of minimally the following documents:

- **Change notification** document making clear reference to the MDCG 2020-16 rev. 4 and Expert Panel opinion and the devices that are covered by the change notification. It shall make clear the rationale and justification of the new different class, in light of the intended purpose. ALL Scenarios.
- **Impact Analysis** of these regulatory documents in relation to the technical documentation that has previously been reviewed or is under review. ALL scenarios
- **Declaration of Conformity (DRAFT)** that will reflect the new classification of the device concerned. ALL scenarios.
- **Classification Justification Statement** will need to be updated to reflect the new classification, including classification rationale and application of classification rules.
- **Parts of the Technical Documentation:** Depending on the scenario that is applicable; in order to demonstrate Annex II and Annex III compliance, Notified Bodies will focus on the changes that have been implemented in the technical documents, as part of the change notification review.**
- **Risk Management File:** The risk management file may need to be updated to reflect the changed requirements for Class B/C as opposed to Class D.
- **Summary of Safety and Performance:** when Class B, an SSP is not required anymore. This can be verified as part of the surveillance schedule.
- **PSUR:** When Class B, there is no need for a PSUR: a PMS Report is required instead. This can be verified as part of the surveillance schedule.

** In general the review strategy of the (changed/updated) technical documentation may depend on the classification of the device and the certification structure compliance coverage that has been established, previously.

After the submitted change notification, and underlying documentation has been reviewed, and this has resulted in a certification decision for the down-classified device, the Notified Body will follow-up on any outstanding actions in the first year of the surveillance cycle. For instance, when (parts of the) technical documentation cannot be verified at the stage of the change notification submission, implementation of the technical documentation review can occur at a later stage. This is determined by every Notified Body on a case-by-case basis.

It is anticipated that the quality management system of the manufacturer is not much affected as a result of the change in classification of the device. The QMS processes that are anticipated to be affected and would require further evaluation are:

- Batch verification process specific for Class D devices at the manufacturer site;
- Review of external documents;
- Reconciliation of stock of existing Class D devices, which were previously placed on the EU market;
- Update of technical documentation affected to the change.
- Review whether the QMS scope of the manufacturer is affected as a result of this change.

These elements can be taken on board when planning for the audit / changing the audit program. Again, the extent of verification is dependent on which scenario plays out and at which stage.

6. Question and Answers:

Q1: Following the expert panel advice and update of MDCG IVD classification guidance as regards SARS-CoV-2 IVDs, what can Notified Bodies now communicate back to their clients, in the interim?

Notified Bodies are encouraged to get acquainted with the updated MDCG 2022-16 (rev 4) for information and determine its impact. Also, it is recommended to read the press release statement from TEAM-NB and updated position paper on this particular topic, as this document reflects the current, harmonized interpretation of Notified Bodies.

Q2: Are Notified Bodies able to change the certification documents themselves, per updated MDCG 2022-16 (rev. 4)? If not, what is expected from the manufacturers to be prepared?

Notified Bodies have met and discussed the impact of the changes of the MDCG 2020-16 (rev.4), more specifically for SARS-CoV-2 devices that have been certified, as well as under application. Notified Bodies have created a common approach, of which parts can be shared with manufacturers through their individual communication channels. In short, manufacturers are expected to provide a change notification document to their Notified Body, that constitutes the following:

- **Change notification document** making clear reference to the MDCG 2020-16 rev. 4 and Expert Panel opinion and the devices that are covered by the change notification. It shall make clear the rationale and justification of the new different class, in light of the intended purpose.
- **Impact Analysis** of these regulatory documents in relation to the technical documentation that has previously been reviewed or is under review.
- **Declaration of Conformity** (DRAFT) that will reflect the new classification of the device concerned.
- **Classification Justification Statement** will need to be updated that reflect the new classification, including classification rationale and application of classification rules.
- **Parts of Technical Documentation:** Depending on the scenario that is applicable; in order to demonstrate Annex II and Annex III compliance, Notified Bodies will focus on the changes that have been implemented in the technical documentation.
- **Updated Risk Management File** (part of the Technical Documentation)**:** The risk management file may need to be updated to reflect the changed requirements for Class B/C as opposed to Class D.

When Class B, an SSP and a PSUR is not required anymore. This can be verified as part of the surveillance schedule.

The review of the updated documentation can either be planned at the time of the submission of the change notification or planned in the upcoming year in the surveillance as scheduled according to the updated sampling plan e.g. consider for the next surveillance cycle after receipt of the change notification; this will be determined by the Notified Body on a case-by-case basis.

Q3: What to do with applications that have been reviewed for Class D, but for which the technical documentation review has not yet started or is pending review?

Also for this particular scenario, Notified Bodies have discussed an approach, although, the resulting actions very much depend on the scenario at hand and will need to be determined by the Notified Body on a case-by-case basis. In general, the following options can be discussed, depending on the stage where the application is at:

- The Class D technical documentation review and executed QMS audit will be finalized, considering the change notification and impact analysis at hand. When no certification decision has been reached on the device as Class D, the Notified Body will consider the change notification and underlying documentation and revise the recommendation accordingly.
- The Class D application review has been finalized but the conformity assessment has not started yet (no technical documentation review and QMS audit has been conducted at the time of the change notification submission). The Notified Body will ask the manufacturer to resubmit the updated technical documentation, per the amended classification. The documentation review and QMS audit will then be rescheduled, per agreed planning.
- The Class D application has been submitted by the manufacturer; however, the application review process has not been completed by the Notified Body; the application will be refused/declined with a specific request to submit a to submit a new IVDR application that considers the appropriate classification (be it Class B or Class C). When re-submitted, the Notified Body will quote per the changed classification.

Q4: Can the changed technical documentation also be reviewed as part of the surveillance cycle, when the original Class D application has been reviewed by the Notified Body?

Yes, this is possible. But the feasibility of this depends on the stage at which the current Class D application is in process. This will need to be determined by the Notified Body on a case-by-case basis.

Q05: what will be done with the EU Technical Documentation assessment certificates that have previously been issued, covering SARS-CoV-2 devices as Class D?

The EU Technical Documentation assessment certificate covering SARS-CoV-2 that is affected as a result of the classification change will be cancelled; voluntary refusal. This is done after receiving the change notification and review of affected documentation is complete. And will be done in accordance with an agreed planning with the manufacturer. Existing SARS-CoV-2 clients with Class D certificates issued need to meet all of their contractual obligations as Class D until the certificate is cancelled. For Technical documentation reviews that are pending, Notified Bodies can decide to issue certificates as Class D for a time limited period or complete? the review to new classification, depending on clients preference. This depends on the scenario and needs to be decided between the manufacturer and the Notified Body on a case-by-case basis.

Q06: What will be done with confirmation letters that have previously been issued covering SARS-CoV-2 devices as class D?

The confirmation letters covering SARS-CoV-2 for professional use will need to be amended to reflect the new classification.