The European Association of Medical devices Notified Bodies

TEAM-NB A.I.S.B.L.
Rue Bawepuce 20
B – 4140 Sprimont - BELGIUM
Phone: +32 475 85 40 45

E-mail: assistant@team-nb.org
Web: http://www.team-nb.org
IBAN BE09 3401 5174 8757
VAT BE 0864 640 677 - RPM Liège

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PRESS RELEASE

Important update on the classification of IVD's intended for screening or detection of SARS-CoV-2; practical consequences for certified devices.

1. Backgrounds

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)].

2. Notified Body interpretation of new requirements for COVID tests

Per the publication of the scientific advice, the IVD expert panel has concluded that while the SARS-CoV-2 virus can still cause serious illness, it no longer poses a life-threatening risk with a significant mortality rate for the general European population. This conclusion has been taken on board by the MDCG that, after consultation with other stakeholders, has updated the MDCG 2020-16, as follows:

- Examples under rationale for rule 1, second indent does not mention SAR-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.
- 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.

For the exact text, reference is made towards MDCG 2020-16 Rev.04 [(2)].

Notified Bodies will now apply the new information from the updated MDCG 2020-16, as of the date of publication. In short, COVID tests will now have a different risk classification as opposed to the aforementioned Class D, ruling these Class B or Class C, depending on the intended purpose. This also means that specific Class D requirements for these devices are not applicable anymore, such as batch verification activities and batch testing by the EU Reference Laboratories and PSUR or SSP requirement, when considered the device is considered Class B. Common Specifications are not mandatory anymore but are still considered to be state of the art; applying CS in the manufacture of COVID test is therefore recommended. Ultimately, this determination needs to be made by the manufacturer and confirmed by the Notified Body on a case-by-case basis. The Notified Bodies will examine the document further and will soon come with a general and compliant approach to accept and process down-classification of COVID tests that have previously been certified through alternative means[(3)]. It will also mean that the previously issued TEAM-NB position paper on classification of SARS-CoV-2 tests[(4)] will be revised. For the moment, affected IVD manufacturers are requested to reach out to their Notified Body to discuss the ramifications of this document.

In addition, it needs to be noted that the classification document now contains a statement that in case of changes in the epidemiological context for any virus or agent, which is not limited to SARS-CoV-2 tests, classification rules 1 or 3 could become applicable and the class of the device revised.

3. Conclusions

The publication of the updated MDCG 2020-16 Rev.04 means that the classification of COVID tests is going to change, per the classification rules of Annex VIII (EU) 2017/746. IVD manufacturers that have COVID tests certified or have these devices in application, are requested to pro-actively reach out to their Notified Body to determine what this change in classification means for them.

Notified Bodies (NBs) are open to and will continue collaborating with IVD manufacturers to ensure a smooth and complete transition of the certification to address the down classification.

(1) https://health.ec.europa.eu/latest-updates/advice-sars-cov-2-request-medical-device-coordination-group-29-january-2025-2025-01-29_en
(2) https://health.ec.europa.eu/latest-updates/update-mdcg-2020-16-rev4-guidance-classification-rules-vitro-diagnostic-medical-devices-under-2025-03-18_en
(3) https://www.team-nb.org/wp-content/uploads/members/M2022/Team-NB-PositionPaper-InterimmeasuresVerifclassD-V1-20221005.pdf
(4) https://www.team-nb.org/wp-content/uploads/2025/01/Team-NB-PositionPaper-Classification-of-SARS-Cov2-20240202.pdf

- **About Team-NB**

Team-NB is the European Association for Medical Devices of Notified Bodies, Team-NB is dedicated to ensure a high level of patients' safety and confidence.

Our three main areas of focus, have been and will remain:

- ❖ The promotion of innovation, but innovation that is backed by solid safety and effectiveness data. The certification of manufacturers' products is essential to continue the confidence in Medical Devices and In-Vitro Diagnostic products.
- ❖ Our support to notified bodies, through our detailed and state of the art guidance documents, ensures a consistent standard is achieved by our members throughout Europe.
- ❖ Ultimately, Team-NB works to ensure continuous improvement of products, leading to increased patient access to safe innovative products.

Our main objectives, have been and will remain:

- ✓ To improve communications with the European Commission, Industry, Competent Authorities and User Groups by acting as a focal point and the single voice of Notified Bodies
- ✓ To promote high technical and ethical standards in the functioning of Notified Bodies
- ✓ To increase competences in decision making processes
- ✓ To make available to the sector a competent work forces as quickly as possible
- ✓ To protect the legal and commercial interests of Notified Bodies in their vital role in the functioning of the three medical device directives.

Team-NB set up **Mirror MDCG-working groups** to allow the members the opportunity to support development of European guidance and enable comments on draft documents in order to coordinate and consolidate input.

Team-NB also set up **task forces** to address specific items in order to harmonise views and come with best practice guides. Today there are 27 tasks forces working on topics such as article 117, classification interpretation, cybersecurity,…

Moreover, the **Team-NB academy** organised several trainings related to the new MDR/IVDR with the aim to help notified bodies deal with new requirements in their assessments. Another purpose is to achieve a better harmonisation among notified bodies thanks to the exchanges that will be favoured during the presentations and the cases studies sessions.
Moreover, **session for harmonisation** has been set up at the senior experts' level to share their experience on burning clinical (MD) and performance (IVD) evaluation topics. The objective is that attendees cascade the info into their organisation to reach all reviewers.
The Team-NB academy has also held several **trainings for manufacturers** on both IVD and MD technical documentation in aim to help them to meet the regulations requirements.

In case of any further clarification needed, please contact : schlemmer(at)team-nb.org.