

Availability and capacity of notified bodies to carry out conformity assessments for COVID-19 related medical devices and *in vitro* diagnostic medical devices

In the [Joint European Roadmap towards lifting COVID-19 containment measures](#) adopted on 15 April 2020, the Commission committed to provide information on the availability and capacity of conformity assessment bodies and to share it with market operators (page 9). In this context, the Commission conducted a survey with notified bodies in charge of the certification of COVID-19-related medical devices and *in vitro* diagnostic medical devices earlier this month. The below document presents the findings and will be inserted on the website of the Commission's Clearing house for medical equipment (COVID-19) and shared with market operators.

1. Legal framework and 'route to the market'

COVID-19 related medical devices are regulated by the Medical Devices Directive 93/42/EEC (MDD). They can also be placed on the market under the Medical Devices Regulation (MDR). COVID-19 tests are *in vitro* diagnostic medical devices and are regulated by the Directive on *in vitro* diagnostic medical devices 98/79/EC (IVDD). They can also be placed on the market under the *In vitro* diagnostic medical devices Regulation (IVDR).

In order to lawfully place on the EU market medical devices and *in vitro* diagnostic medical devices under the scope of the above mentioned Directives or Regulations, these products must be CE-marked after performing a conformity assessment to confirm that they comply with the relevant legal requirements of the applicable EU legislation.

For certain classes of medical devices and *in vitro* diagnostic medical devices, the manufacturer needs to involve a notified body in the conformity assessment procedure. The COVID-19 related medical devices and *in vitro* diagnostic medical devices that require involvement of a notified body are:

- Medical devices that are classified as Class I, only if supplied sterile and/or with measuring function, Class IIa, Class IIb and Class III under Annex IX of the MDD.
- Medical devices that are classified as Class I, only if supplied sterile, with measuring function, and/or that are reusable surgical instruments, Class IIa, Class IIb and Class III under Annex VIII or the MDR)
- Devices for self-testing as defined in Article 1(2)(d) of the IVDD.
- *In vitro* diagnostic medical devices classified as Class A sterile, Class B, Class C and Class D under Annex VIII the IVDR.

Conformity assessment procedures can include audits of manufacturers and/or critical suppliers/subcontractors, testing or review of technical documentation. The applicable conformity assessment routes will depend on the risk class of the device and are established in:



- Article 11 of the MDD establishing the conformity assessment routes for different classes of devices. The specific steps of the conformity assessment procedures are defined in the respective Annex:
 - Annex II: full quality assurance system
 - Annex III: EC type-examination
 - Annex IV: EC verification
 - Annex V: production quality assurance
 - Annex VI : product quality assurance

- Article 52 of the MDR establishing the conformity assessment routes for different classes of devices. The specific steps of the conformity assessment procedures are defined in the respective Annex or part of:
 - Annex IX: conformity assessment based on a quality management system and on an assessment of technical documentation
 - Annex X: conformity assessment based on type-examination
 - Annex XIA: conformity assessment based on production quality assurance
 - Annex XIB: conformity assessment based on product verification

- Article 9 of the IVDD establishes the different conformity assessment routes for different classes of devices. In particular, for devices for self-testing, manufacturers have to follow the conformity assessment established in Annex III(6), based on examination of the design.

- Article 48 of the MDR establishing the conformity assessment routes for different classes of devices. The specific steps of the conformity assessment procedures are defined in the respective Annex:
 - Annex IX: conformity assessment based on a quality management system and on an assessment of technical documentation
 - Annex X: conformity assessment based on type-examination
 - Annex XIA: conformity assessment based on production quality assurance

Once the notified body verifies the compliance of the product with the relevant requirements of the applicable EU legislation, it will issue the appropriate certificate.

2. Availability of notified bodies

Notified bodies are designated by the relevant national authorities to perform specific conformity assessment procedures and thus to issue the related certificates. The designation specifies the annexes of the relevant EU legislation, corresponding to the specific conformity assessment procedure, and the types of products for which they can carry out conformity assessment activities. The types of products are identified by an alphanumeric code¹.

¹ For explanation on designation codes under the MDD or IVDD please see the NBOG BPG 2009-3 - www.doks.nbog.eu/Doks/NBOG_BPG_2009_3.pdf and for designation codes under the MDR and IVDR please see [Commission Implementing Regulation \(EU\) 2017/2185](http://www.doks.nbog.eu/Doks/NBOG_BPG_2009_3.pdf).



The list of designated notified bodies is available in the Commission's NANDO information system <https://ec.europa.eu/growth/tools-databases/nando/>. Please see below a link to the specific lists under the different applicable EU legislation:

- List of notified bodies for the MDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
- List of notified bodies for the IVDD: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20
- List of notified bodies for the MDR: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
- List of notified bodies for the IVDR: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

3. Capacity of notified bodies

In order to gather information on the capacity of notified bodies concerning COVID-19 related devices, a survey has been carried out from 7 May to 13 May 2020 among the notified bodies designated to carry out conformity assessments under the Directives and the Regulations. Each notified body was requested to assess its capacity for different procedures and classes of devices. Thirty-seven notified bodies, out of a total of fifty-five, replied to the questionnaire and the results are presented below.

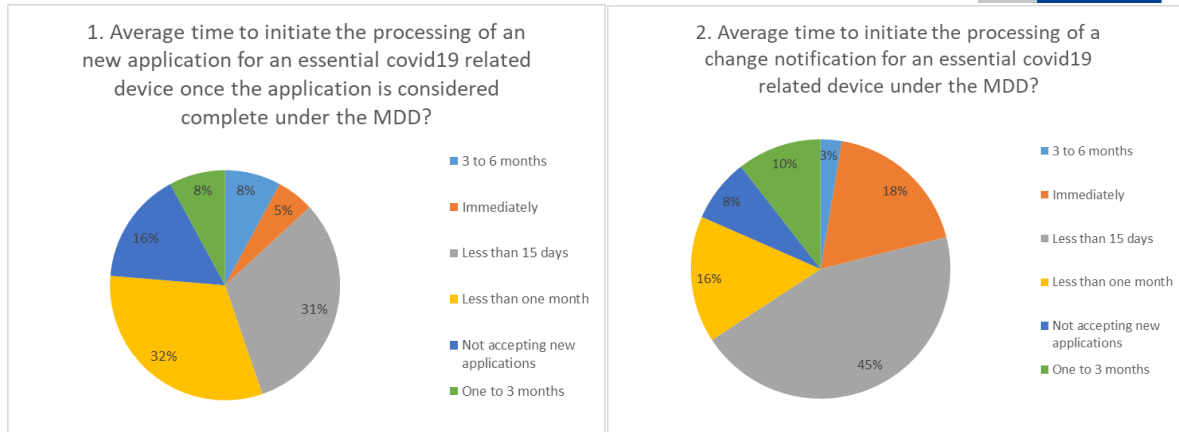
3.1. Average time to initiate a procedure

Before a conformity assessment starts, the manufacturer usually needs to send an application to the notified body. The procedures to apply to different notified bodies are usually publicly available in the body's website. Once the notified body receives an application, it assesses whether it is complete for the relevant procedure to start.

In the survey notified bodies were asked about the average time to initiate the processing of an application (i.e. waiting list) either for a new device to be certified (from an existing or new client) or for a change on a certificate to be approved, so-called change notification (i.e. to add a supplier or subcontractor or add a product to the certificate).

Notified bodies replied (see graphs n°1 and 2 below) that they have a shorter waiting time to process change notifications (63% will take less than 15 days) in comparison with new applications (36% will take less than 15 days). A similar number of notified bodies replied that these procedures will take longer than one month to process 16% for new applications vs 13% of change notifications.

It is important to highlight that 16% of notified bodies are not taking any new applications. Such percentage is reduced to 8% when considering applications related to a change notification.



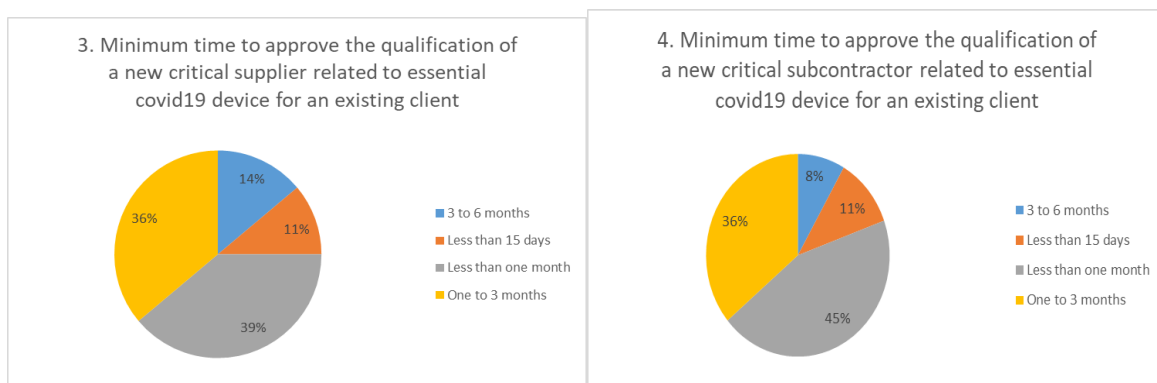
3.2. Minimum time to complete a procedure

Notified bodies were asked to provide the minimum time needed to finalise a full procedure for conformity assessment in relation to medical devices and *in vitro* diagnostic medical devices related to COVID-19. A full procedure could consist on a change notification or a new application. All questions asked were based on a best-case scenario by which the technical documentation and the quality management system are in line with requirements and no shortcomings are found during the assessment.

3.2.1. Minimum time to complete a procedure related to change notifications for a COVID-19 related device

A change notification is a change in the current certification of an existing client. These change notifications can be related to new suppliers, new subcontractors or new devices to be added to the product range (either from the same category/group of devices or not). This option is only available to those manufacturers that are currently manufacturing devices already certified by the same notified body. In most cases, they will have a certificate covering the full quality assurance system and therefore working already under an implemented quality management system which has been certified.

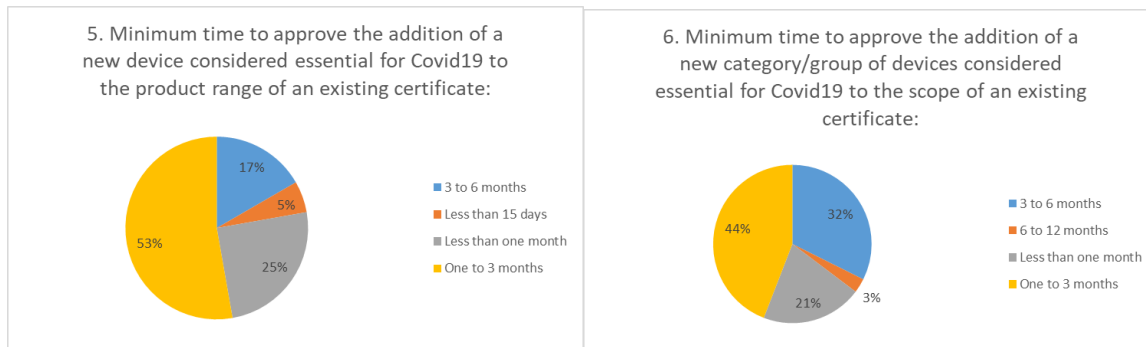
With regard to the minimum time to approve the qualification of a critical supplier or subcontractor (see graphs n° 3 and 4 below), the responses provided are very similar. However, it seems that the qualification of a new critical supplier could take slightly more time than a subcontractor.





With regard to the minimum time to approve the addition of a new device related to COVID-19 to the product range covered by a current certificate (see graph n°5 below), the survey indicates that in the majority of cases it will take one to 3 months.

Regarding the inclusion of a device included in a category currently not covered by the certificate (see graph n°6 below), the time increases slightly, being more numerous the notified bodies that consider that it will take 3 to 6 months.



It must be noted that notified bodies indicated that the information provided for the above questions are a rough estimate and that in case of higher classes, the necessary time could increase further.

3.3. Minimum time to complete a procedure to certify a COVID-19 related device

With regard to new applications, notified bodies were asked about different conformity assessment routes for different classes of devices under different EU legislations.

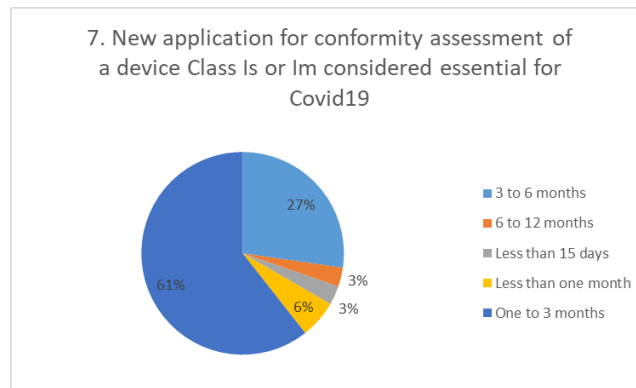
The below sections refer to new clients that have never worked with a given notified body before in the highly regulated sector of medical devices and *in vitro* diagnostic medical devices. This presupposes that all the systems established by the manufacturer have to be assessed by the notified body for the first time, which could in principle result on a need for additional time for completion.

3.3.1. Conformity assessments for a new client under the MDD for COVID-19 related devices

It is important to note that in the current context, notified bodies can see their ability to carry out conformity assessments reduced, given the limited capability to carry out on-site audits² possibly to be replaced by alternative temporary extraordinary measures.

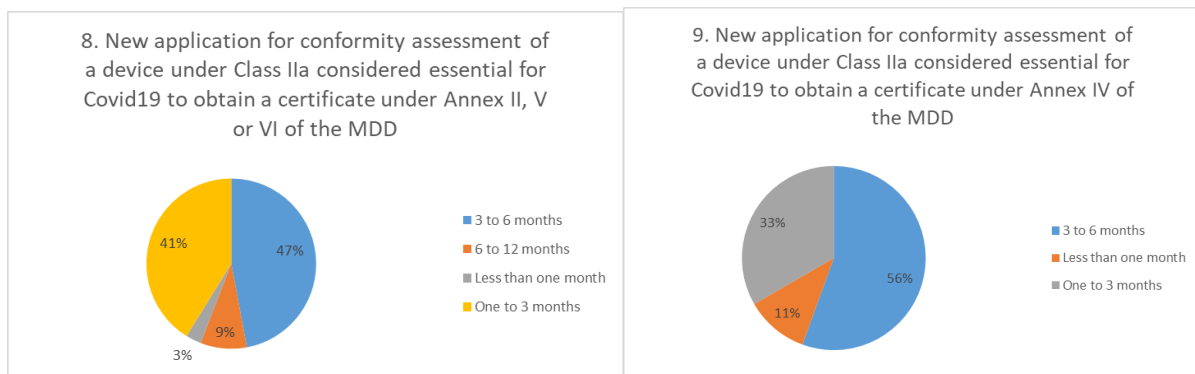
The graph below (n°7) shows that the most common time needed to complete a conformity assessment procedure for a Class I sterile or with measuring function is one to 3 months.

² See [MDCG 2020-4](#) - Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions



The graphs below (n°8 and n°9) show the minimum time for completion of conformity assessment for Class IIa COVID-19 related devices, which is on average one to 6 months.

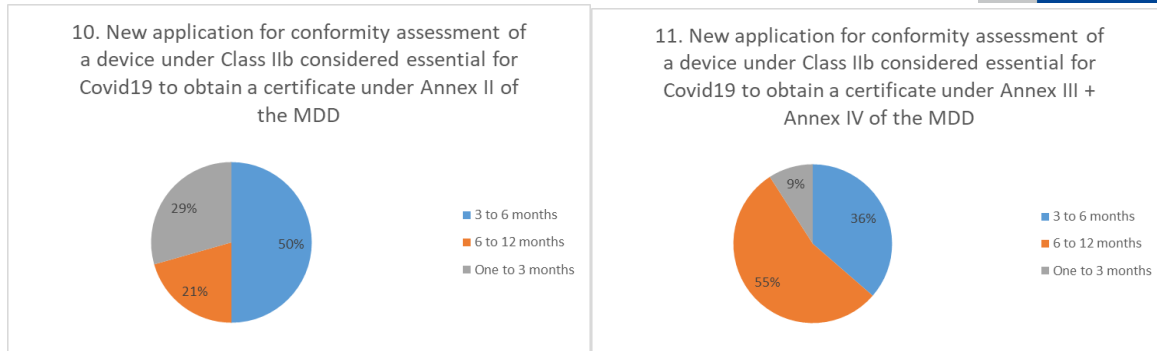
From the information provided, certificates under Annex II, V or VI of the MDD (quality management system certificates) would be issued in less time than those issued under Annex IV (EC verification). It should also be noted that there is a limited number of notified bodies designated to perform activities under this conformity assessment route. This could play a role in the capacity of those notified bodies.



With regard to Class IIb COVID-19 related devices, the graphs below (n°10 and n°11) provide evidence that the minimum time for completion of the conformity assessment differs from the procedure (i.e. the relevant Annex) applied.

For Annex II, a 29% of notified bodies would issue the certificate in less than 3 months while the majority of notified bodies would take 3 to 6 months. However, for procedures described under Annex III and IV, the average time expressed is 6 to 12 months.

As indicated above, the limited number of notified bodies designated to carry out activities under Annex III and IV could play a role in the increased time for completion.

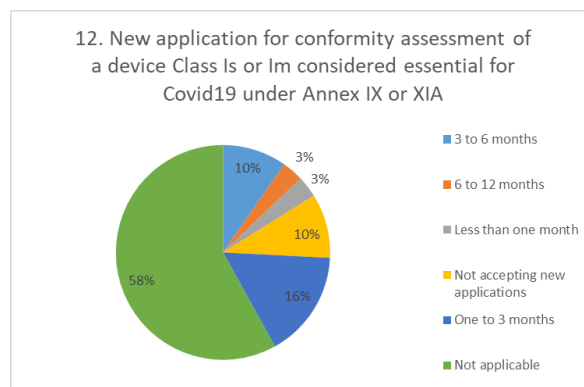


3.3.2. Conformity assessments for new clients under the MDR for COVID-19 related devices

It is important to note that there is a limited number of notified bodies designated under the MDR in comparison to those designated under the MDD. This could play a role in the capacity of those notified bodies.

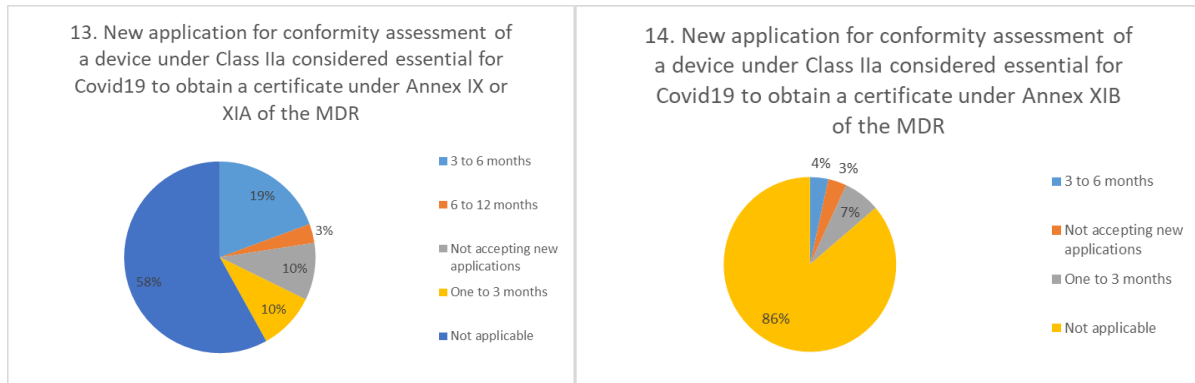
In addition, in the current COVID-19 context, notified bodies will often not be able to carry out on-site audits. This is likely to have an impact on the minimum time to complete certification.

The graph below (n°12) shows that the time needed to complete a conformity assessment procedure for a Class I sterile or with measuring function is in most cases one to 3 months. It must be stressed that around 10% of notified bodies are not currently accepting applications under this route.



The graphs below (n°13 and 14) show that the minimum time for completion of conformity assessment for Class IIa COVID-19 related devices is on average one to 6 months under Annex IX or XIA of the MDR. It should be also noted that 10% of the notified bodies are not accepting new applications.

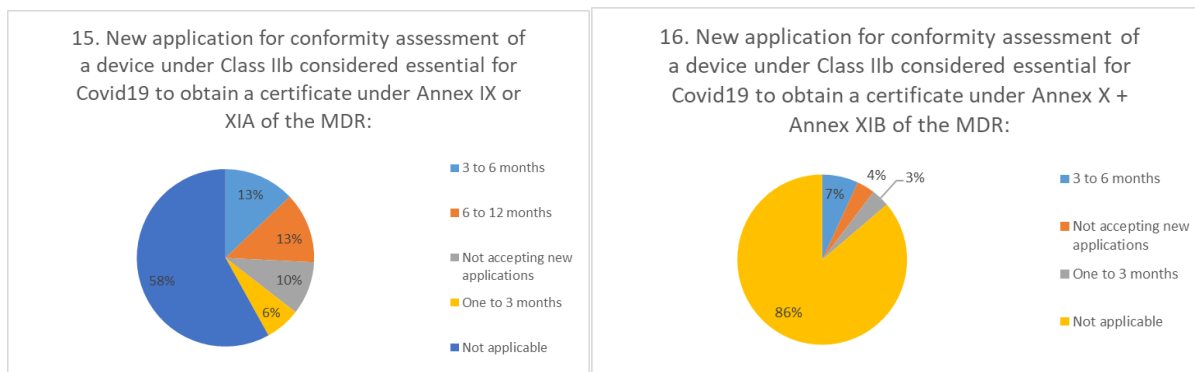
Most of the notified bodies replying to the survey are not designated to carry out activities under Annex XIB of the MDR (product verification). Two notified bodies indicated that the minimum time is one to 3 months, while another notified body indicated 3 to 6 months. It should be also noted that 7% of the notified bodies are not accepting new applications.



With regard to Class IIb COVID-19 related devices, the graphs below (n°15 and 16) indicate that the minimum time for completion of the conformity assessment differs from the procedure applied.

For Annex IX or XIA, 26% of notified bodies would issue the certificate in more than 3 months and less than 12 months. It should be also considered that 10% of notified bodies are not currently accepting applications under this route.

However, for procedures described under Annex IXB, two notified bodies indicated that the minimum time is 3 to 6 months, another notified body indicated one to 3 months. It should also be considered that 3% of notified bodies are not currently accepting applications under this conformity assessment route.



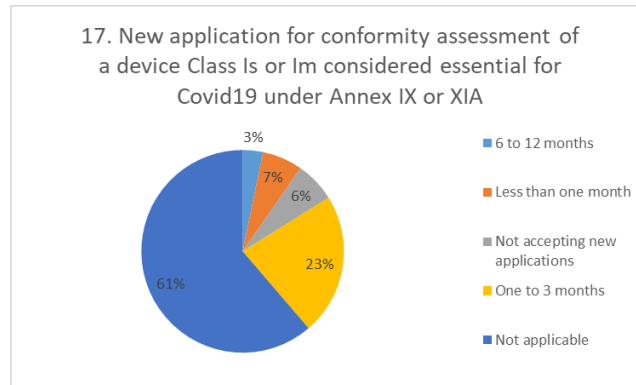
3.3.3. Conformity assessments for existing clients under the MDR for COVID-19 related devices

This section refers to new certificates under the MDR from existing clients of the notified body. Even if all the procedures under the MDR must be followed for an existing client, it is expected that existing clients are more familiar with the notified body procedures and legal requirements.

As stated in section 2.2.2, the limited number of notified bodies designated under the MDR, and the current context of travel restrictions could affect the capacity of notified bodies designated to carry out conformity assessments under the Regulation.

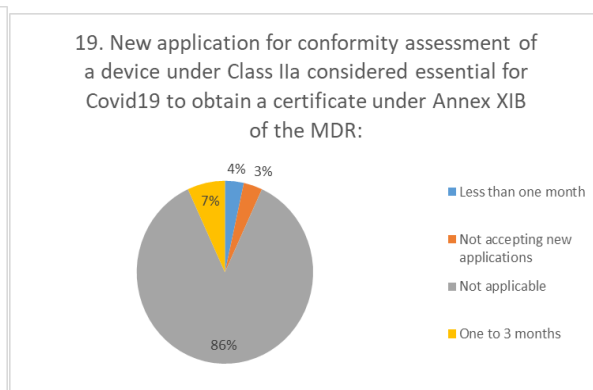
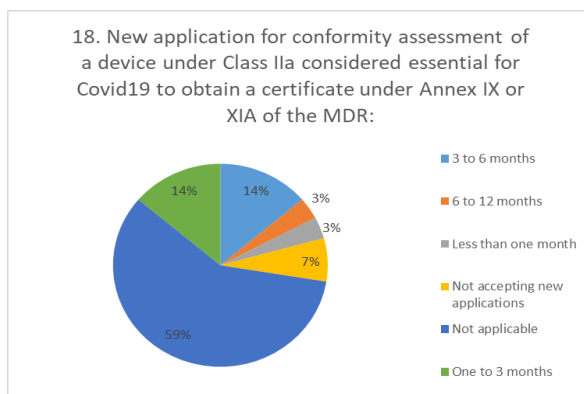


The graph below (n°17) shows that the time needed to complete a conformity assessment procedure for a Class I sterile or with measuring function is in most cases one to 3 months. It must be noted that 6% of notified bodies are not currently accepting applications from existing clients under this route.



The graphs below (n°18 and 19) show the minimum time for completion of conformity assessment for Class IIa COVID-19 related devices, which is on average one to 6 months under Annex IX or XIA of the MDR. It must be noted that 7% of the notified bodies are not accepting new applications from existing clients.

Most of the notified bodies replied that they are not designated to carry out activities under Annex XIB of the MDR (product verification). Two designated notified bodies indicated that the average time to complete conformity assessments is one to 3 months, another notified body indicated less than one month. Lastly, 3% of the notified bodies are not accepting new applications from existing clients.

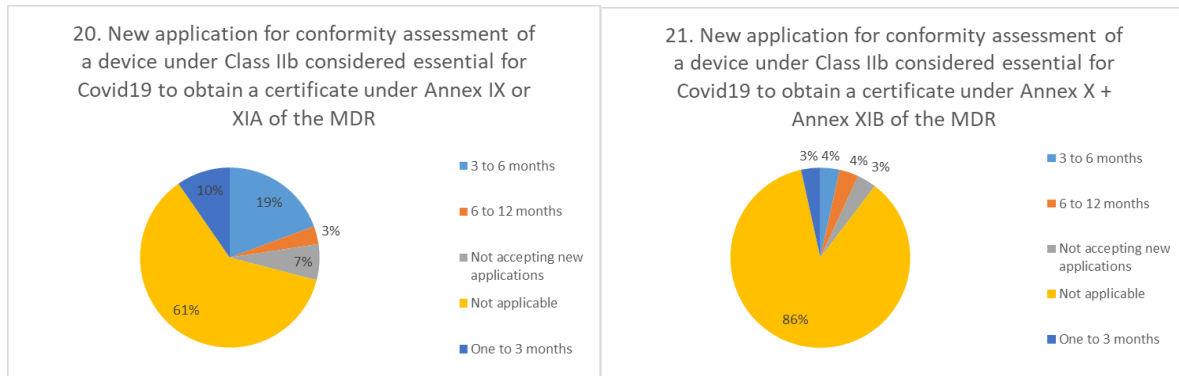


With regard to Class IIb COVID-19 related devices, the graphs below (n°20 and 21) show that the minimum time for completion of the conformity assessment differs from the procedure applied. For Annex IX or XIA, a 29% of notified bodies would issue the certificate in less than 6 months. This being said, 7% of notified bodies are not currently accepting applications from existing clients under this route.

However, for procedures described under Annex IXB, only 3 notified bodies indicated the minimum time to finalised the certification and the time indicated varies greatly between

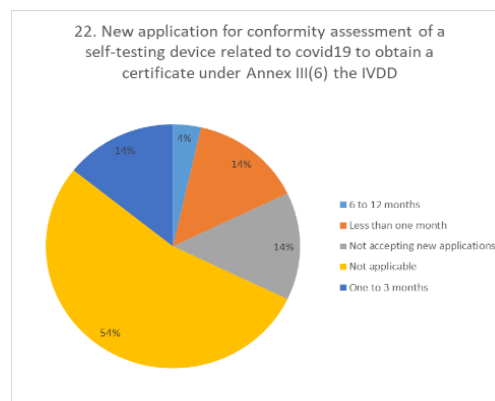


them. This being said, 3% of notified bodies are not currently accepting applications under this route.



3.3.4. Conformity assessments for existing clients under the IVDD for COVID-19 related devices

With regard to devices for self-testing under the IVDD (see graph n°22), notified bodies expect that under best case scenario situation the time for processing applications will be less than one month (14%) or less than 3 months (14%).



3.3.5. Conformity assessments for existing clients under the IVDR for COVID-19 related devices

Regarding conformity assessment procedures under the IVDR, only one notified body is currently accepting applications for Class A sterile, Class B and Class C devices. In its responses, this notified body indicated that the time for completing the full conformity assessment will be less than one month. Two other notified bodies indicated that they are not currently accepting applications.

With regard to possible COVID-19 Class D devices, it should be noted that conformity assessments under the IVDR are subject to necessary appointments to the expert panels and of EU reference laboratories (IVDR Article 110(7)). Given that the Regulation is not fully applicable and some of these are not yet in place, such conformity assessment procedures cannot be completed at the moment.