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| Editor : | **Team-NB/NBCG Med** | Adoption date | 09/11/2021 | Version 1 |

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| **Significant changes according to Article 110 (3) of Regulation EU 2017/746** |

1. **Introduction**

Article 110(3) of the In-Vitro Diagnostics Medical Device Regulation (EU) 2017/746 (IVDR) states that devices which have a valid certificate issued by a notified body under In-Vitro Diagnostics Directive 98/79/EC may be placed on the market or put into service after the date of application of the IVDR under certain conditions and no later than 26 May 2024.

Questions 8 and 9 of the CAMD Transition Subgroup guidance: “FAQ – IVDR Transitional provisions, V1.0 of 17. January 2018” state that the certificates covered by IVDR Article 110(3) include “all certificates which are commonly issued by notified bodies with reference to the Council Directives IVDD”.

Conditions referred to in the first paragraph require that no significant changes in design or intended purpose of a device be performed after the date of application of the IVDR.

The recent EU Commission proposal (2021) 627 on transitional provisions extends the application of article 110(3) to additional devices. At the time this paper is being written, it is not known yet if the proposal will be accepted by Council (Member States) and European Parliament and when it will become applicable.

1. **Scope**

This position paper is intended to provide clarification on the Notified Bodies interpretation of the changes to a device that should be considered a “significant change in design or a significant change in the intended purpose” under IVDR Article 110(3). Assessments should be made on a case-by-case basis. This position paper does not address “substantial changes” ‘notifications required according to Sections 2.4, 4.11 and 5.2 of Annex IX of the IVDR.

1. **Changes to Directive certificates**

It is important to highlight that no issuing of new IVDD certificates, including modified, amended, or supplemented certificates, is allowed under IVDR Article 110(3).

If the manufacturer wishes to make a “significant change in design or intended purpose” as per IVDR Article 110(3) it is not possible under the Directive. The implementation of such a change would require a new submission under the Regulation.

1. **Notified Body assessment of changes' significance in accordance with IVDR Article 110(3)**

In line with agreed arrangements for notification of changes between the manufacturer and the notified body according to the IVDD (e.g. contractual relationships, approved procedures) changes and their implementation will be verified by the notified body as part of the surveillance activities or following a manufacturer’s submission for prior approval. The outcome of this verification will determine whether a certificate in accordance with IVDD remains valid according to Article 110 IVDR.

If a change is not a significant change in design or intended purpose under IVDR Article 110(3), the implementation of such a change is allowed during the transitional period.

For instance, administrative changes of organisations are considered in principle as non-significant. This includes changes of the manufacturer’s name, address or legal form (legal entity remains) or changes of the authorised representative.

Furthermore, all changes not having an impact on the design or the intended purpose of the device can be regarded as not significant in the meaning of IVDR Article 110(3). This is the case for example of relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers, or of certain changes of the quality management system, provided that the conditions for which the conformity assessment certification was granted are maintained. Nevertheless, such changes continue to be subject to the agreed notification procedure identified in the first paragraph of the current section. The manufacturer should always remain responsible for providing evidence that all the above-mentioned changes do indeed neither affect the design nor the intended purpose.

On the other hand, when the change is likely to affect the design or the intended purpose of the device, the significance of such a change must be assessed on a case-by-case basis.

The assessment of a proposed change by using the main flowchart and any of the applicable sub-charts in the Annex, is intended to assist notified bodies in deciding whether or not a change in the design or intended purpose of the device is to be considered significant under IVDR Article 110(3).

The flowcharts are divided into a main chart and four sub-charts (A to D). There are four questions in the main chart that are linked to these four sub-charts with more detailed questions. The change is considered a non-significant change of design or intended purpose per IVDR Article 110(3) if the answer to every question in a sub-chart leads to “nonsignificant change” also when returning to the main chart.

If any sub-chart delivers the result “significant change”, the change being assessed is a “significant change in design or intended purpose” of a device according to the IVDR Article 110(3).

# **ANNEX**











