The European Association of Medical devices Notified Bodies	**Team-NB/ NBCG Med Position Paper**	

Editor :	**Team-NB/NBCG Med**	Adoption date 14/07/2022	Version 1

Notified body approach for the Technical Documentation assessment approach of multiplex in-vitro diagnostic devices

Disclaimer

This paper is intended for Notified Body use only.

It has been endorsed by members of Team-NB, the European Association for Medical Devices of Notified Bodies and by the Notified Body Coordination Group for Medical Devices (NBCG-Med), as established by Art 49 of Regulation (EU) 2017/745 and Art 45 of Regulation (EU) 2017/745. The NBCG-Med is composed of representatives of all notified bodies for medical devices and IVDs.

The paper is not a European Commission document and cannot be regarded as reflecting the official position of the European Commission, Competent Authorities for Medical Devices (CAMD) or Medical Device Coordination Group (MDCG).

If EU Commission, CAMD or MDCG publish new relevant documents or make changes to existing ones, this paper may be updated/withdrawn to align with the position expressed in aforementioned documents.

Scope

The scope of this position paper is to provide a notified body common approach to the Technical Documentation assessment of multiplex IVD devices.

Background

Multiplex *in vitro* diagnostic (IVD) devices are defined as devices in which two or more targets/markers are simultaneously detected through a common procedure.

Multiplex IVD devices are sold as one device, as one Basic UDI-DI with one intended purpose statement. The intended purpose can include the detection of several (100+) targets/markers e.g. several allergens or bacteria.

Due to the potentially large number of targets/markers included in the intended purpose, the assessment of the Technical Documentation of these devices and the review of the clinical data included to support the detection of each individual targets/markers, is challenging.

Considerations

MDCG 2019-13 *Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation* does not specifically include the possibility to sample within a Basic UDI-DI. However due to the potentially large number of targets/markers it may not be possible for the notified body to assess the supporting data for each marker individually and a risk based sampling approach should be considered.

In these instances, the notified body review should focus on the verification of the technology used in the multiplex IVD device for the detection of the targets/markers. A risk-based approach should then be taken when deciding which marker specific data should be reviewed. Based on the targets/markers identified, the device could be classified into multiple classes, priority should be given to the review of the markers with the highest class.

If there are concerns derived from multiple deficiencies during the initial review, the notified body may decide to sample from additional analytes or update the sampling plan during the certification cycle.

This sampling approach can be taken for markers/target that would be classified as class C and B. Technical documentation for all class D markers would be reviewed.

The approach used and rationale applied by the notified body to assess the Technical Documentation of these devices should be recorded in the conformity assessment documentation.

Some examples of the approach to be taken for the Technical Documentation assessment are included in the next section.

Examples

- A Mass spectrometer Microbial Identification System claiming the identification of 200+ bacteria: the Technical Documentation assessment should focus on the design, verification and validation of the reading system. The review of the data supporting clinical performance of the system should be done on a sampling basis with a risk-based approach.
- Immuno Solid-phase Allergen Chip (ISAC) technology for specific IgE test against > 100 allergens: the Technical Documentation assessment should focus on the design, verification and validation of the reading system; since the device risk class is likely to be the same for all analytes in the panel, the notified body would need to justify a sampling approach as to which individual allergen performance/clinical data is reviewed, as a way to build the confidence over the quality of TD for entire panel/device.
- Multiplex device for respiratory pathogen panels can include multiple targets/markers SARS Cov 2 (class D) and Influenza A B (class B) Adenovirus, Pneumonia (Class C/B).