IMDRF IVD WG Comment Form	Date: 5.4.20	Document: **IMDRF/IVD WG (PD1)/N64: Principles of In Vitro Diagnostic (IVD) Medical Devices Classification**

Name/Organization	Line number	Section	Comments	Proposed change	Resolution
AdvaMedDx	General	N/A	On behalf of AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), we respectfully submit these comments to this public consultation. AdvaMedDx member companies produce advanced, *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing IVD companies in the United States and abroad.	No changes recommended.	
AdvaMedDx	General	N/A	We support the draft issued for public consultation. We appreciate that the document maintains the fundamental principles for classification embodied in the GHTF IVD classification document. The current GHTF IVD Classification document is well accepted in several countries (e.g., Australia, Brazil, Canada, Japan, South Korea, and Singapore). Significant modifications are not needed at this time. Any changes should be made with caution so that manufacturers and regulators can continue to consistently classify devices and allocate appropriate resources to their development and review.	No changes recommended.	

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2 **Type of comment:** **ge** = general **te** = technical **ed** = editorial

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AdvaMedDx	General	N/A	The current classification approach as outlined in the consultation should be maintained. Specifically, we agree with a risk-based classification approach based on the product's intended use. We believe classification approaches not based on intended use should be avoided, as we do not believe such schemes allow for a flexible, least burdensome approach for the development of new products and technologies.	No changes recommended.	
AdvaMedDx	General	N/A	To the extent there is temptation to adopt aspects of the IVDR, we recommend against such an inclination. The current approach provided in the IMDRF document is reasonable and forward thinking. Adoption of an IVDR-like approach may add unnecessary burdens to regulators that could derive from the yet-to-be implemented IVDR-like approach.	No changes recommended.	
AdvaMedDx	295	5.0 General Principles	We recommend adding language to clarify that IVDs, including accessories, should be classified based on their own risk and not the risk of the parent device. Allowing separate regulation of IVDs independent from the parent device allows for a risk-based, least-burdensome approach. For example, the U.S. Food and Drug Administration (FDA) demonstrates this approach as evidenced in section 513(f) of the Federal Food, Drug, and Cosmetic Act, which states, "the Secretary shall … classify an accessory based on the risks of the accessory when used as intended…to provide a reasonable assurance of safety and effectiveness of the accessory". The U.S. FDA's Guidance on Accessory Classification further articulates this approach by stating, "[S]ome	We recommend adding the following language: "To ensure a risk-based approach, the classification of each medical device, including accessories, should be determined based on its own risk and not that of the parent device."	

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			accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class." This risk-based least burdensome approach focuses on high-risk devices and makes wise use of the regulatory authority's resources.		
AdvaMedDx	329-331	6.0	We would recommend revising to be consistent with Rule 7, 6.1 for the classification of controls without assigned values by deleting the statement in this section (Section 6.0) indicating that such controls could be placed in the same class of the IVD reagent.	Stand-alone control materials with no assigned values intended for use with multiple or single analytes <u>will be classified as Class B.</u>	
AdvaMedDx	516	Rule 5	We would propose adding an example for clarification: There is a group of specimen preparation reagents such as individual antibodies, both polyclonal and monoclonal, specific receptors proteins, ligands, nucleic acid sequences, and similar reagents that, through specific binding or chemical reaction with substances in a specimen, are used for identification and/or quantification of a single ligand or target (antigen, protein, etc.) in human specimens. When one of these specimen preparation reagents is intended by the manufacturer as suitable for inclusion into *in vitro* diagnostic procedures relating to a specific examination, these reagents should be considered as for general laboratory use, and included in the examples under Rule 5.	We would propose Including the following as an example under Rule 5: <u>Specimen preparation reagents such as individual antibodies (both polyclonal and monoclonal), specific receptors proteins, ligands, nucleic acid sequences, etc. for identification and/or quantification of a single target in human specimens.</u>	

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AdvaMedDx	565-569	9.1	Rule 7: IVD medical devices that are controls without a quantitative or qualitative assigned value will be classified as Class B.	No change recommended: We believe this language is appropriate and would also propose that it be used in Section 6.0 (see comment above).	

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