IVD Medical Device Classification Tool

Dr. Soe Ye Yint Tun

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Motivation

- SCH Medical Device CoE choose “Principles of In Vitro Diagnostic (IVD) Medical Devices Classification” as part of the core curriculum
- The document describe classification rules in paragraphs (plain text)
- Required the users to remember the rules so that the users can know where to start when classifying IVD medical devices.

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Purpose

- To help the users to understand the classification rules easier
- To allow step by step approach in classifying IVD medical devices without relying on memory.

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Methodology

- This tool is developed based on the "Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG/N64FINAL:2021)"
- To help the users in narrowing down the classification rules for an IVD medical device of interest.
- Since there are multiple phrases with different meanings in some classification rules, we have added numbering system to identify the exact phrase of the rule (e.g. Rule 1.1, Rule 1.2).

Rule No.	Phrase
Rule 1.1	Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs or any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration
Rule 1.2	Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, disease with a high or suspected risk of propagation

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Methodology

- We identified the keywords from the classification rules and created a data table to filter the rules by similar keywords.
- After refining the similar keywords, we have three groups of keywords (Step-1, Step-2 and Step-3) which are used to narrow down the related classification rules for individual device.

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Using the tool

- The user should fully understand the original IMDRF document before using this tool to be able to classify the IVD medical devices correctly because this tool focus only on the rules of the IMDRF document.
- There are other important sections in IMDRF document such as Definitions, General Principles, and Recommendations and Factors Influencing IVD Medical Device Classification, etc.
- This tool is not designed to replace the original document but help the users in navigating the rules easier.

SCH Medical Device Regulatory Center Website

https://www.ebdiagnostics.org/center/index.do

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Link to CoE training website

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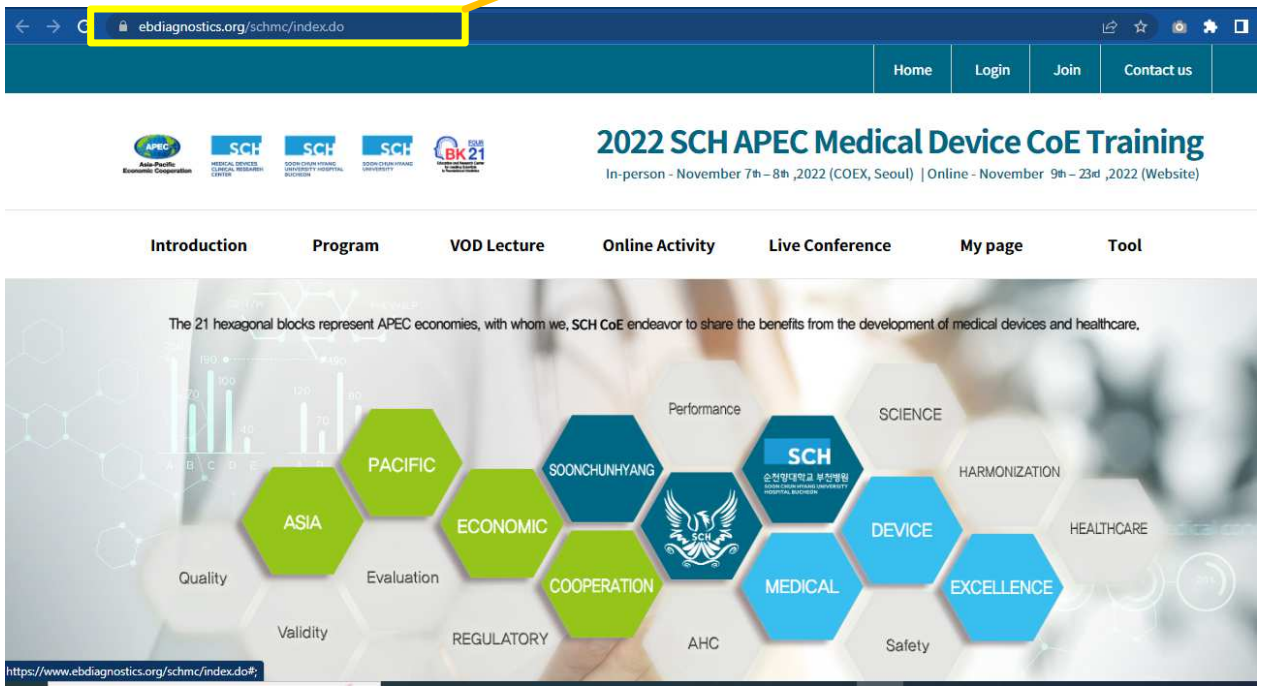
CoE training website

https://www.ebdiagnostics.org/schmc/index.do



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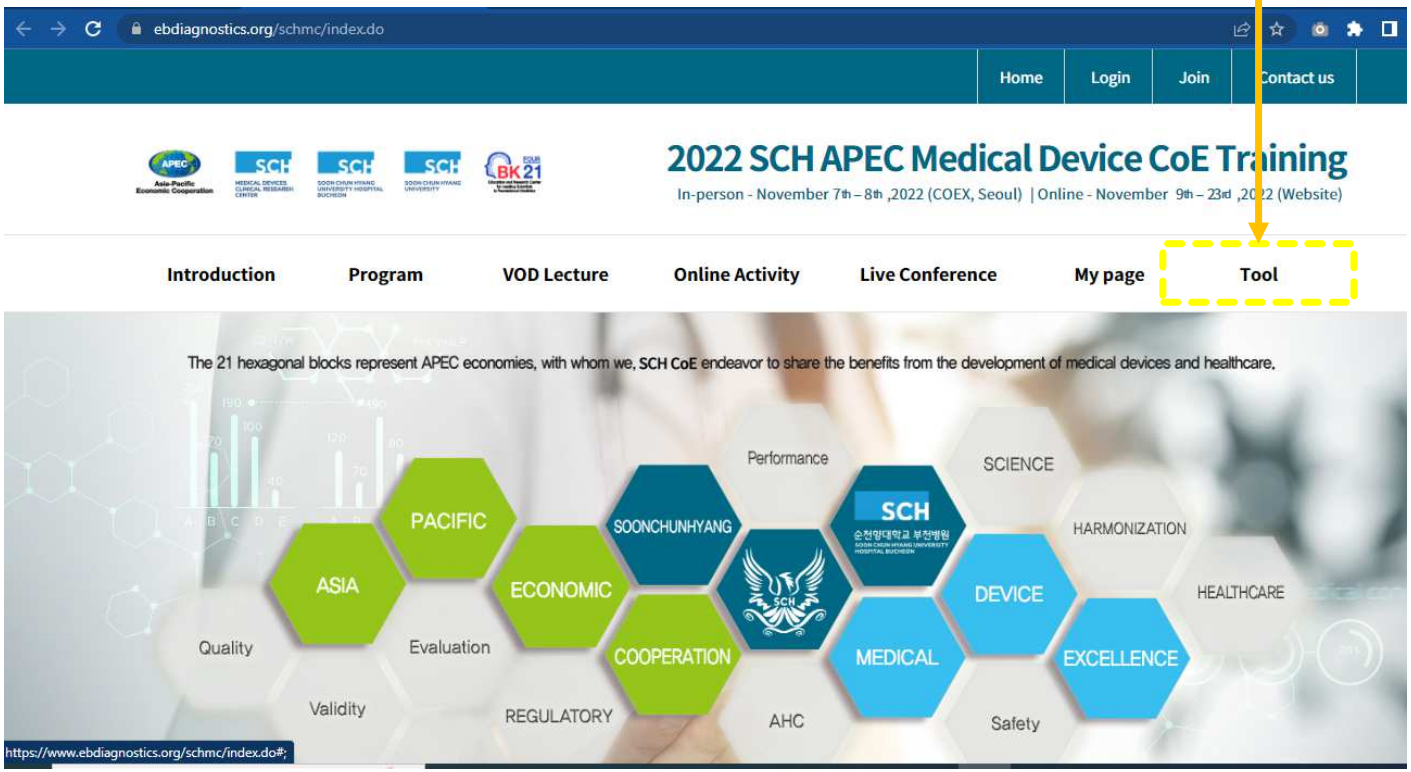
IVD medical device classification tool



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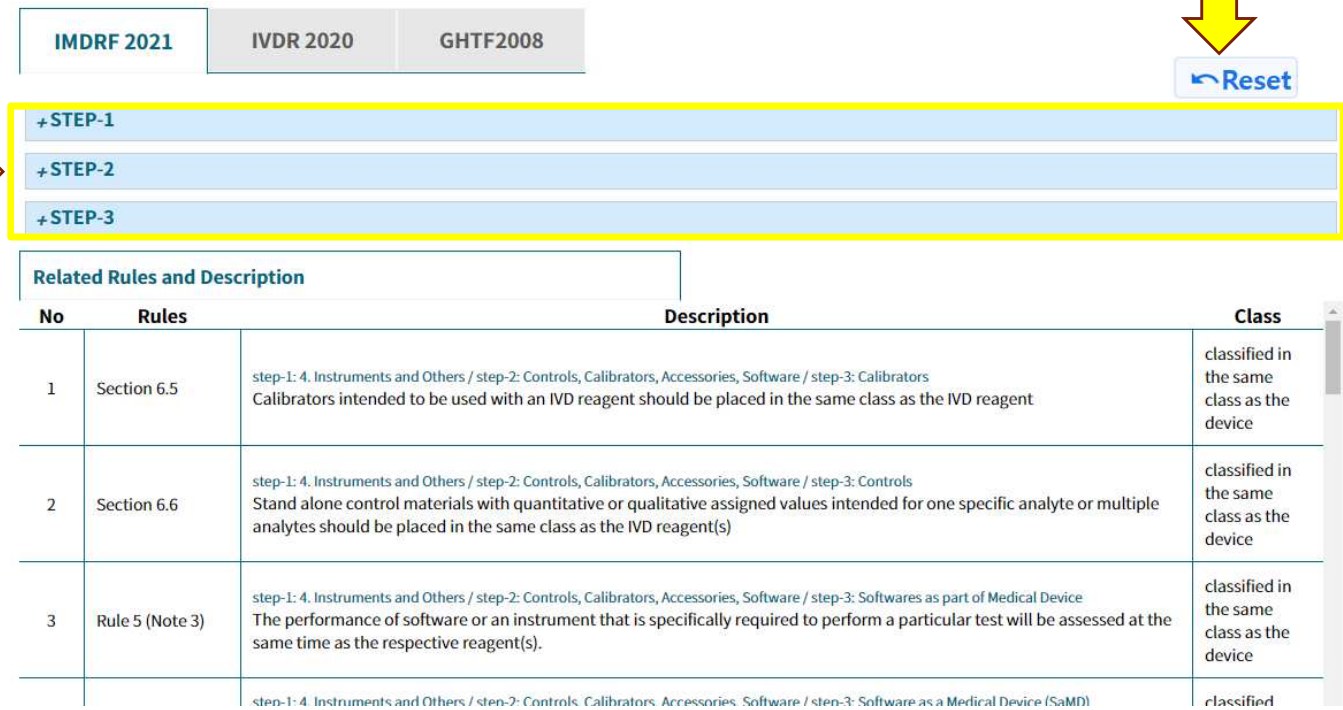
How to use

- Start classifying the IVD medical device by selecting keywords in the STEP-1, STEP-2, and STEP-3.

- Use "Reset" to clear all selection.



No	Rules	Description	Class
1	Section 6.5	step-1: 4. Instruments and Others / step-2: Controls, Calibrators, Accessories, Software / step-3: Calibrators Calibrators intended to be used with an IVD reagent should be placed in the same class as the IVD reagent	classified in the same class as the device
2	Section 6.6	step-1: 4. Instruments and Others / step-2: Controls, Calibrators, Accessories, Software / step-3: Controls Stand alone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes should be placed in the same class as the IVD reagent(s)	classified in the same class as the device
3	Rule 5 (Note 3)	step-1: 4. Instruments and Others / step-2: Controls, Calibrators, Accessories, Software / step-3: Softwares as part of Medical Device The performance of software or an instrument that is specifically required to perform a particular test will be assessed at the same time as the respective reagent(s).	classified in the same class as the device
		step-1: 4. Instruments and Others / step-2: Controls, Calibrators, Accessories, Software / step-3: Software as a Medical Device (SaMD)	classified

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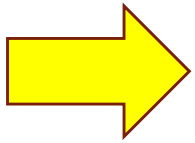
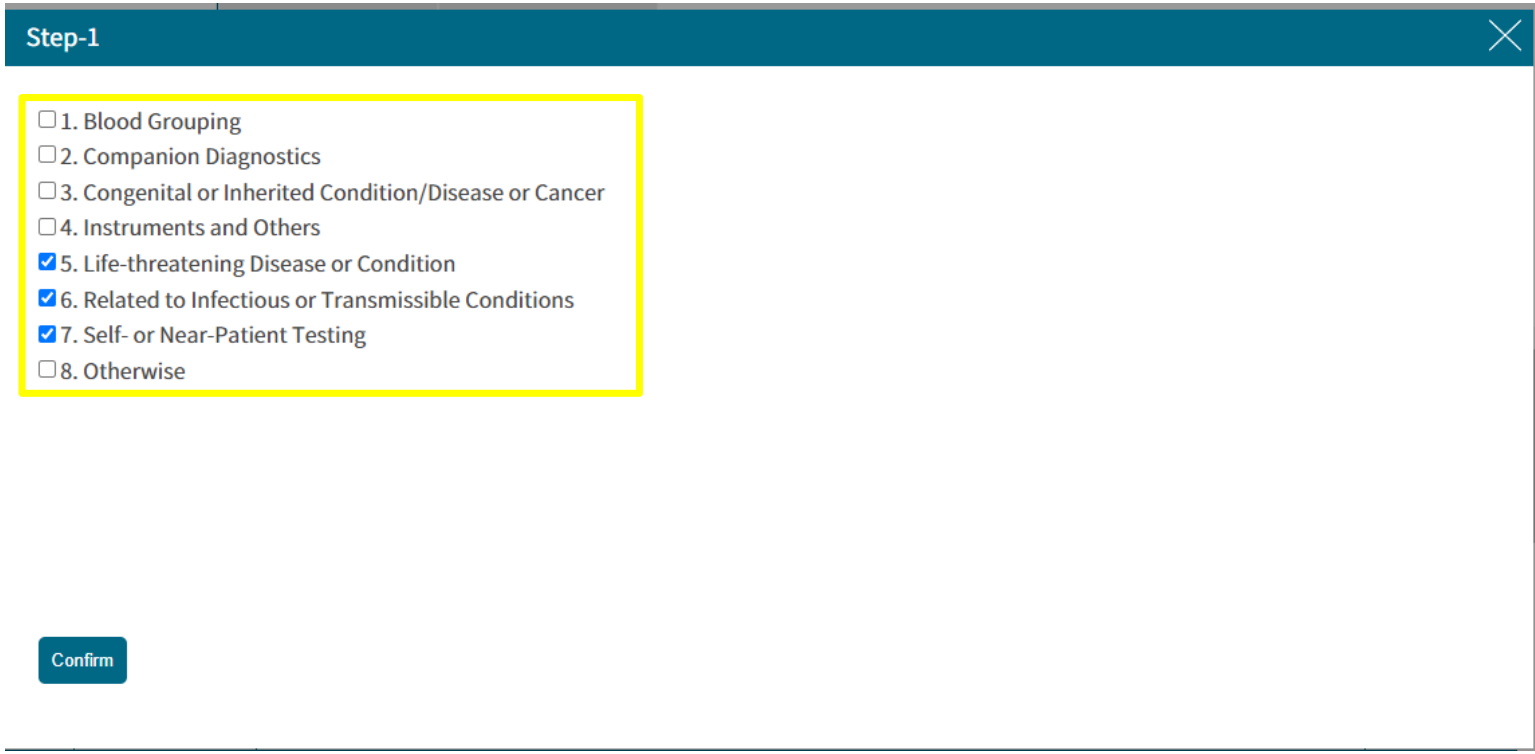
How to use

- Multiple keywords for each STEP can be chosen.





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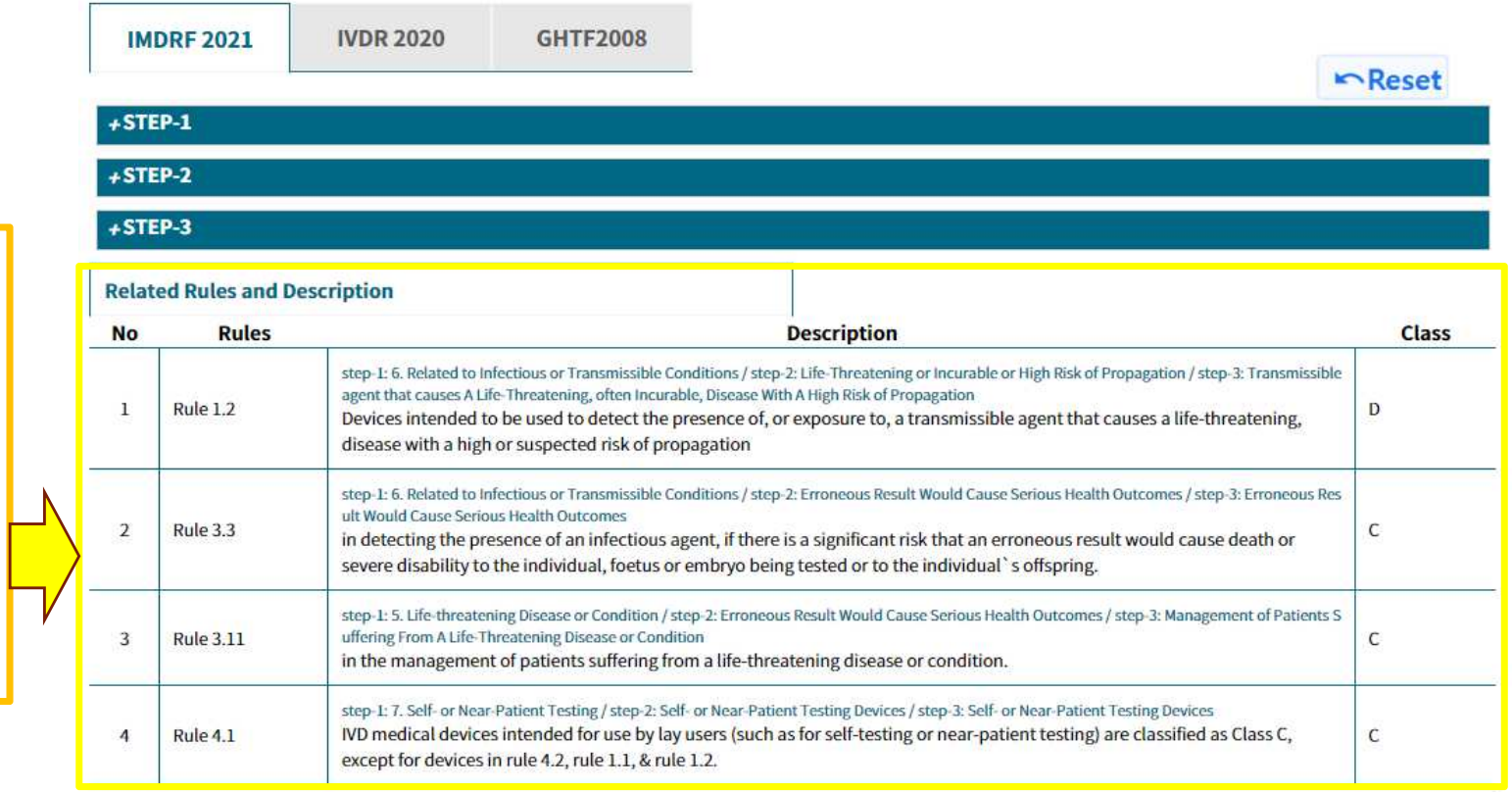
How to use

- After STEP-3, the table below will show only the related rules for the IVD medical device being classified.
- The user can then decide which class the device should be put into.



No	Rules	Description	Class
1	Rule 1.2	step-1: 6. Related to Infectious or Transmissible Conditions / step-2: Life-Threatening or Incurable or High Risk of Propagation / step-3: Transmissible agent that causes A Life-Threatening, often Incurable, Disease With A High Risk of Propagation Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, disease with a high or suspected risk of propagation	D
2	Rule 3.3	step-1: 6. Related to Infectious or Transmissible Conditions / step-2: Erroneous Result Would Cause Serious Health Outcomes / step-3: Erroneous Result Would Cause Serious Health Outcomes in detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested or to the individual`s offspring.	C
3	Rule 3.11	step-1: 5. Life-threatening Disease or Condition / step-2: Erroneous Result Would Cause Serious Health Outcomes / step-3: Management of Patients Suffering From A Life-Threatening Disease or Condition in the management of patients suffering from a life-threatening disease or condition.	C
4	Rule 4.1	step-1: 7. Self- or Near-Patient Testing / step-2: Self- or Near-Patient Testing Devices / step-3: Self- or Near-Patient Testing Devices IVD medical devices intended for use by lay users (such as for self-testing or near-patient testing) are classified as Class C, except for devices in rule 4.2, rule 1.1, & rule 1.2.	C

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More tools

- In addition to IMDRF 2021 version, we have also developed the tools for
  - IVDR 2020 (Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746) and
  - GHTF 2008 (GHTF/SG1/N045:2008)

  as well.

Example Case

Rapid Antigen test for diagnosis of COVID-19 infection (Self-testing) in the early pandemic.

Intended purpose – Diagnosis of COVID-19 In early pandemic

- COVID-19 infection is regarded as a transmissible agent that causes a life-threatening disease with a high risk of propagation.
  - According to rule 1.2, the test kit should be classified as **Class D.**
- It is also a self-testing device.
  - According to rule 4.1, the test kit should be classified as **Class C.**
- However, the recommendation in Section 8 of IMDRF document states if more than one of the classification rules applies to the IVD medical device, the device should be allocated to the highest class indicated which in this case should be **Class D**.

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Thank you

If you have any feedbacks regarding this tool, feel free to reach at schmd.coe@gmail.com.