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Your Guide to 8 New & Revised Concepts to the IVDR

Definitions (Article 2)

01 GENETIC TESTING

Although with some bending of rules, these tests are currently overseen by the IVDD, they will now be formally defined as IVDs, falling under "concerning the predisposition to a medical condition or a disease" (Definition 2c) and listed specifically as Class C (Annex VIII, Classification rules 2.3).

In addition, for genetic testing and counseling, IVDR requires the Member States to establish measures that ensure the provision of adequate information to patients. Manufacturers of in-house tests may face additional requirements in the specific Member States. (Article 4)

02 DEVICES FOR NEAR-PATIENT TESTING:

Intended for testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional. Self-testing is excluded.
(Definition 6)

03 COMPANION DIAGNOSTIC:

A device that is essential for the safe and effective use of a corresponding medicinal product (e.g., identifying potential users, and identifying patients likely to suffer adverse reactions).
(Definition 7)

04 SINGLE-USE DEVICE:

Intended to be used during a single procedure. The concept of single-use devices has already been introduced in the MDD but is new for IVDs.
This particular condition only impacts user information and registration of the device, as this information must be mentioned on the label, in the IFU, and the registration information for the IVD's unique device identifier (UDI).
(Definition 9)

05 FALSIFIED DEVICE:

A false presentation of identity, source, and/or CE marking certificate. However, unintentional noncompliance or infringements of intellectual property are not in the scope of this definition. This particular product status is important because it obligates distributors and importers to report falsifications and enables authorities to take appropriate action.
(Definition 10)

06 KIT:

A set of components packaged together and intended to be used to perform a specific examination of a part thereof. This definition codifies the interpretation in MEDDEV 2.14/1 and will help determine borderline cases where devices work together in an IVD procedure.
(Definition 11)

07 CLINICAL EVIDENCE:

A set of definitions to facilitate understanding of the requirements for clinical evidence.
(Definitions 36-62)

08 COMMON SPECIFICATIONS (CS):

Technical and/or clinical requirements that provide a means to comply with the requirements applicable to a device, process, or system. (In the IVDD, Common Technical Specifications (CTS) were intended to apply to Annex II List A or Annex II List B, but in reality, only CTS for Annex II List A IVDs were ever published. The new CS complete the requirements for List B.) (Definition 74; also, Article 9)

To learn more, read our blog for further examination of these new and revised concepts.

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