edma DIAGNOSTICS FOR HEALTH

Position Paper

CONCEPT OF AN IVD KIT

Definition and labelling

20 October 2015

Introduction:

The concept of an in vitro diagnostic kit has become increasingly relevant in discussions related to the revision of the IVD Directive; therefore EDMA aims to set a common ground for the perception and terminology of such an IVD medical device.

Definition

In the currently applicable European legislation available for in vitro diagnostic medical devices, ***Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD)*** the following definition is available for determining what constitutes an IVD:

'in vitro diagnostic medical device` means any medical device which is a reagent, reagent product, calibrator, control material, ***kit,*** *instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:*

- concerning a physiological or pathological state, or

- concerning a congenital abnormality, or

- to determine the safety and compatibility with potential recipients, or

- to monitor therapeutic measures.

Apart from stating that a kit is an in vitro diagnostic medical device there is no further explanation or definition provided in the IVDD.

However, a definition of an IVD kit is included in the standard ***EN ISO 18113-1:2011 on In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirement***. This international standard is harmonised under the IVDD which means that the technical details included in the normative text of this standard support the legal compliance with the European legislation for IVD MDs as provided in the Annex Z of the standard.

According to EN ISO 18113-1:2011, **an IVD kit is "a set of reactive components that are packaged together and intended to be used to perform a specific IVD examination".**[1] [2]

Typical kit components include reagents (such as antigen or antibody solutions, enzymes, buffer solutions and diluents), calibrators and/or control materials as well as other articles and materials.

Please consult Annex I of this document for a visual representation of an IVD kit.

[1] The definition of an IVD kit was already established in the superseded version of the IVD MD labelling standard, namely by EN 375:2001, therefore the concept has a history of almost 15 years.

[2] The proposal of the Council of the European Union for a *Regulation on in vitro diagnostic medical devices* introduces a definition for 'kits' – see 8(a) on page 6 of Council document 9770/15 dated 12 June 2015 - which is based on the one included in EN ISO 18113-1:2011

The concept of an IVD kit

The components packaged together in an IVD kit are intended by the manufacturer to be used together and are all essential for conducting a particular diagnostic test. When in this configuration, the individual components of the kit cannot be considered an IVD medical device on their own.

However, a manufacturer might also wish or need to sell any of the components which are part of this kit (e.g. solutions, calibrators etc.) **individually**, **separately from the kit.** In this case such components are considered IVD medical devices in their own right and should be labelled as such including the CE mark. This concept will be clarified in the upcoming IVD Regulation[3].

The sales packaging of an IVD kit corresponds to the **outer container** as defined in EN ISO 18113-1:2011 being "used for the packaging of the immediate container or containers of an IVD medical device", namely the individual vials or bottles of reagent materials which are defined as the kit components.

Since it is the IVD kit that is considered as the IVD medical device and not its components, the whole kit should undergo a conformity assessment procedure and be CE-marked at the end. The components of an IVD kit can but do not need to bear a CE mark.[4]

Labelling of the IVD Kit

As the IVD Kit is actually the IVD medical device, all requirements of the IVDD (e.g. the labelling essential requirements as provided by Annex I B.8.4 of the IVD Directive) should be considered for the IVD kit label (i.e. the device label) and not for its components.

As such, the kit outer container label has to comply with all the requirements of Annex I.B 8.4. of the IVD Directive.

Component labels (this applies only to components not placed on the market separately from the kit)

Given the specific characteristics and often small dimensions/ space limitations of the IVD kit components, it is not practicable, nor realistic to include extensive information on the label of a component[5] of an IVD kit except the information that is required for the safe and proper use.

Information that is considered essential for the safe and proper use of a kit component may include:

- Identification of the component (using a name, letter, number, symbol, colour or graphics in the same manner on all labels and in the instructions for use) – Essential Requirement (ER) B.8.4(b) of Annex I, IVDD
- Batch code (If a kit contains different components bearing different batch codes, the batch code indicated on the outer container shall enable the individual batch code of each component to be traced from the manufacturer's production record.) – ER B.8.4(d) of Annex I, IVDD

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[3] European Commission's proposal for an IVD Regulation 2012/0267 (COD), 26 Sep 2012
Annex I, 17.2. Information on the label
17.2. xviii) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section

[4] See EDMA Questions and Answers document No 7 on CE Marking: Marking of components published in November 2000, revised in June 2003

[5] See 4.2 Identification of kit components of EN ISO 18113-2:2013 In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use

- Expiry date – ER B.8.4(e) of Annex I, IVDD
- Particular storage and/or handling information – ER B.8.4(h) of Annex I, IVDD
- Appropriate hazard warnings – ER B.8.4(j) of Annex I, IVDD

The information on the manufacturer / authorised representative is not considered to be essential for the safe and proper use, therefore it is not required by the IVDD to be affixed on the component label; it is given on the outer packaging label of the device (namely the kit label) and/or in the instruction for use.

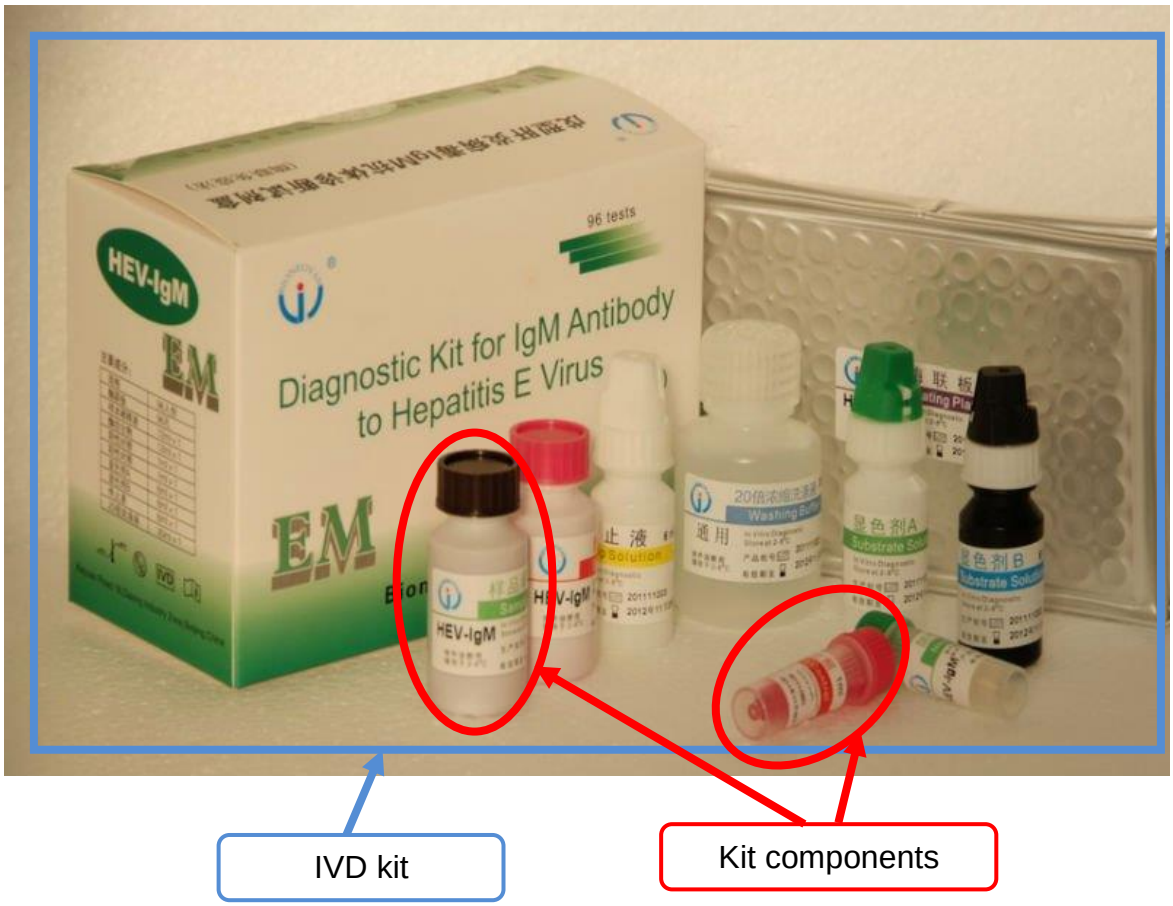
References:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (IVDD)

European Commission's proposal for an IVD Regulation 2012/0267 (COD), dated 26 Sep 2012

Council of the European Union – Proposal for a Regulation on in vitro diagnostic medical devices No 9770/15, dated 12 June 2015

Annex I



A single reagent vial may contain only a small volume (as low as 0.5-1.0 ml) and may then have extremely small dimensions.