Sharing Best Practices – Medical Device Manufacturer Perspectives: **ISO13485**

2020-10-22

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ISO13485:2016 (Third edition, 2016-03-01)

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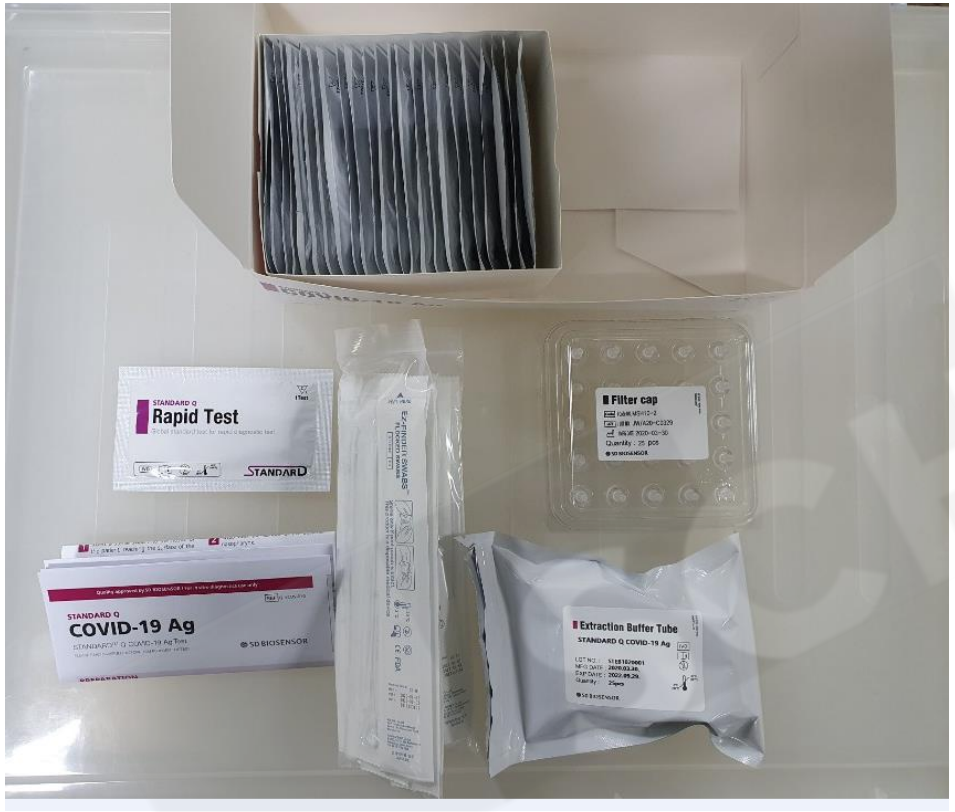
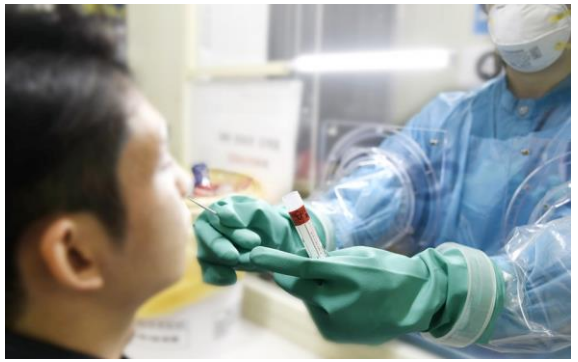
COVID-19 Rapid Test Kit



Ex) Contents of COVID-19 Rapid Ag Test kit

1) Test device
2) Buffer tube
3) Filter cap
4) Sterile swab
5) Instructions for use



-Purpose of sterile swab
It intends to collect a nasopharyngeal swab sample.

MEDDEV 2.14/1 revision 2 January 2012

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A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES

1.1 Definition of an IVD

Article 1(2) (b) of the IVDD defines an IVD as:

*'**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."

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-Essential characteristics of an IVD

1. The principal intended purpose of an IVD is to **provide information on** one or more of the medical purposes

2. The IVD may provide this information either **alone or in combination** with other devices or products

3. The IVD is used ***in vitro*** **for the examination of a specimen** derived from the human body and where such specimen is never reintroduced into the body.

4. The IVD is used *in vitro* for the examination of a specimen derived from **the human body.**

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IVD

1.2 Accessories

Directive 98/79/CE, article 1.2 (c) defines an accessory as *"an article which, whilst not being an IVD, is intended specifically by its manufacturer **to be used together** with a device to enable that device to be used in accordance with its intended purpose"*

*Directive 98/79/CE, article 1.1 states that "This Directive shall apply to **in vitro diagnostic medical devices** and **their accessories**. For the purposes of this Directive, accessories **shall be treated as in vitro diagnostic medical devices** in their own right. Both in vitro diagnostic medical devices and accessories shall hereinafter be termed devices."*

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1.3 Specimen receptacles and products used for the collection of specimens

IVD

1.3.1 Specimen receptacles

Article 1(2) (b) of the IVDD states that:

*"**Specimen receptacles** are considered to be **in vitro diagnostic medical devices**.*

'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination."

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1.3 Specimen receptacles and products used for the collection of specimens

1.3.2 Products used to obtain specimens

not IVD

a) Without intended direct contact with the human body

A product intended to **transfer the sample**, but which is not specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination, is usually **not considered to be an IVD** (*e.g.* plastic pipettes to transfer blood drop from finger to rapid test)

not IVD

b) With intended direct contact with the human body

Invasive sampling devices or those which are **directly applied to the human body** for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall **not be considered to be accessories to in vitro diagnostic medical devices** (Art 1.2.c) (e.g. needles, lancets, lancing devices, mouthtubes, swabs, urine collection bags for babies). These products are regarded as being devices within the scope of Directive 93/42/EEC.

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not IVD

1.4 Products for general laboratory use

Article 1(2) (b) of the IVDD states that:

*"Products for general laboratory use **are not in vitro diagnostic medical devices** unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination."*

1.5 Products for research use only

For further guidance on RUO, please consult MEDDEV *2.14/2 rev.1: IVD Guidance: Research Use Only products*

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IVD

1.6 IVD kits

The definition of an IVD includes ‘kit’ as being an IVD in itself. The IVDD does not give a definition of 'kit', but it is generally agreed that a ‘kit’ consists of more than one component that are made available together and intended to be used to perform a specific IVD examination.

A ‘kit’ with a principal intended purpose falling within the definition of an IVD medical device may contain:

a) IVD medical devices (*e.g.* antibody, antigen, coated ELISA plates, specimen receptacles), which may be either:

- CE marked under the IVDD in their own right allowing them to be also marketed separately, or
- not CE marked,
- a combination of both CE marked and not CE marked.

b) a combination of IVD medical devices and :

- medical devices (*e.g*. lancet, swab), which must be CE marked according to Directive 93/42/EEC;
- other products, such as products for general laboratory use (*e.g.* pipette for transferring a patient sample), which shall not be CE marked;
- food products (*e.g.* chewing gum added for inducing a patient reaction in order to obtain a specific sample), which shall not be CE marked.

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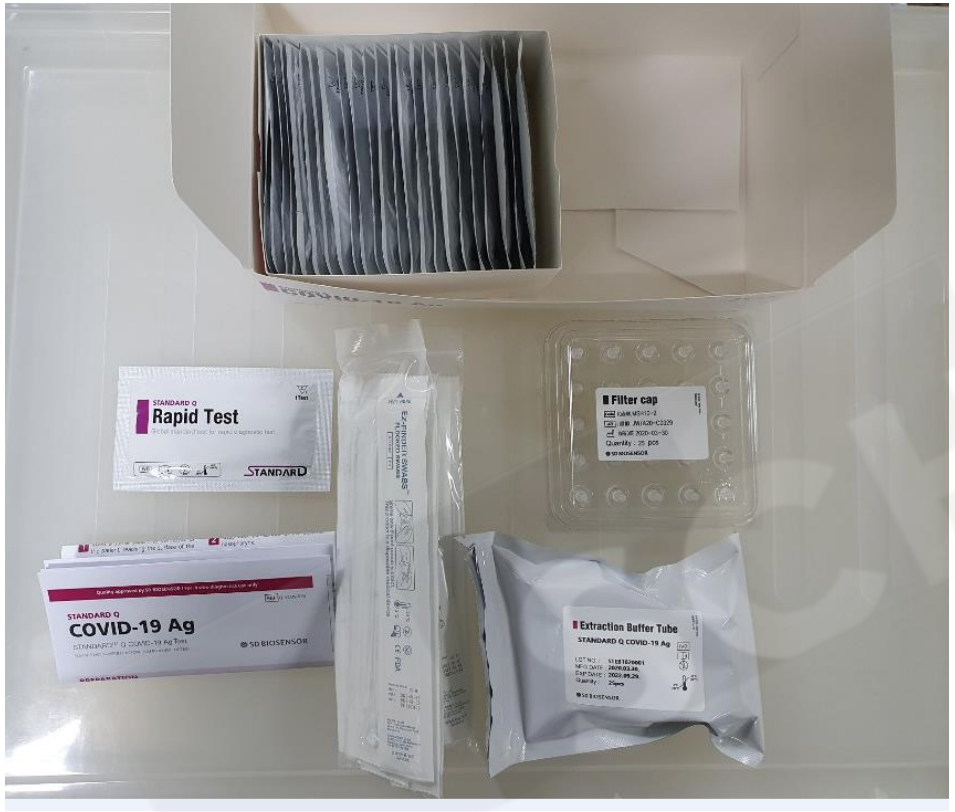
1.7 Control Materials

	IVD	Remarks
Calibrators/Controls included in the kit	**Kit is an IVD**	Calibrators and controls with assigned values must be traceable
Stand alone calibrators/controls (either as part of a kit or provided separately) used to confirm/define the validity criteria of one or several IVD Assay	**IVD**	Calibrators and controls with assigned values must be traceable If the control material includes control values for parameters listed in List A or List B of Annex II, the control material shall be classified according to the highest Classification
Specific EQA materials including materials (stand alone calibrators) used for an external quality assurance system	**Not IVD**	Reference Recital (9) of 98/79/EC
Reference material of higher order	**Not IVD**	Metrological traceability required

COVID-19 Rapid Test Kit



Ex) Contents of COVID-19 Rapid Ag Test kit IVD

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4) Sterile swab not IVD
5) Instructions for use

1.3.2 Products used to obtain specimens

not IVD **a) Without intended direct contact with the human body**

A product intended to **transfer the sample**, but which is not specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination, is usually **not considered to be an IVD** (*e.g.* plastic pipettes to transfer blood drop from finger to rapid test)

not IVD **b) With intended direct contact with the human body**

Invasive sampling devices or those which are **directly applied to the human body** for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall **not be considered to be accessories to in vitro diagnostic medical devices** (Art 1.2.c) (e.g. needles, lancets, lancing devices, mouthtubes, swabs, urine collection bags for babies). These products are regarded as being devices within the scope of Directive 93/42/EEC.

[ISO13485] Purchasing process for sterile swab

Find swab candidate

Evaluate the supplier

Select the supplier

Change

Change Control Procedure

<Regulatory requirement for sterile swab>
-Medical Device (93/42/EEC), not IVD (98/79/EC)
-Sterile validation
-conformity assessment by notified body

<Criteria>
a) based on the **supplier's ability** to provide product that meets the organization's requirements;
b) based on the **performance** of the supplier;
c) based on the **effect** of the purchased product on the quality of the medical device;
d) proportionate to the **risk** associated with the medical device.

Monitoring the supplier

Input

Re-evaluation the supplier

Verification of purchased product : Inspection

Purchasing Procedure

Non-fulfilment of **purchasing requirements** shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The **extent of verification activities** shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

Thank you