



**CONFORMITY ASSESSMENT ROUTES PURSUANT TO DIRECTIVE
98/79/EC ON IN VITRO DIAGNOSTIC MEDICAL DEVICES**

This is a guide about the different available conformity assessment routes pursuant to Directive 98/79 on *In Vitro* Diagnostic Medical Devices to prove that your devices comply with the Essential Requirements that such standard imposes and after that affix the CE marking to your products to denote such conformity.

What does an In Vitro Diagnostic Medical Devices mean?

Pursuant to directive 98/79 EC it 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,*
- *to monitor therapeutic measures.*

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.

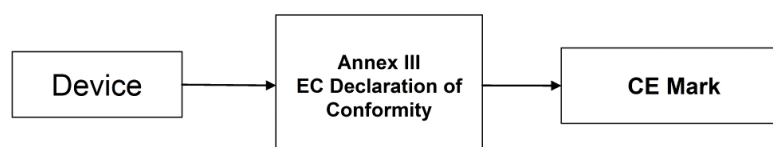
Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination.

What does Conformity Assessment Routes mean?

To be able to prove that your products comply with the Essential Requirements, you must use a proper conformity assessment route for the type of device you produce. This conformity assessment route is made up of a series of steps to follow in order to prove that all the applicable essential requirements have been used.

We show below the different possibilities in order to prove that your products (in this case *In Vitro* Diagnostic Medical Devices) are manufactured in conformity with the Essential Requirements. Such "Conformity Assessment Route" will depend on the classification of the product in question.

General IVD Devices other than devices for Self Testing or devices appearing in Annex II





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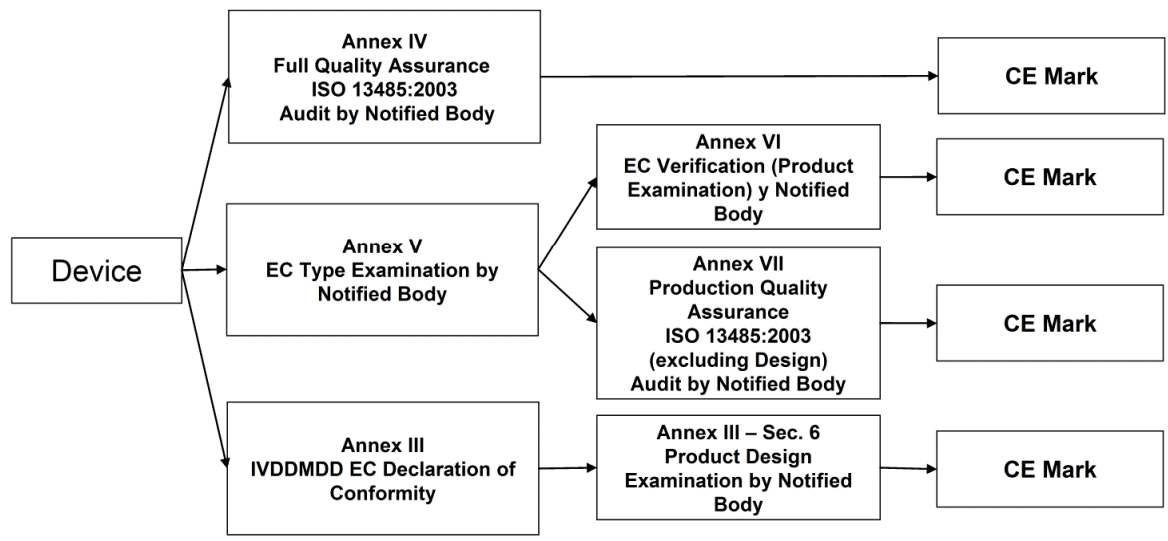
Medical Device Consultants

Fact Sheet N° 3

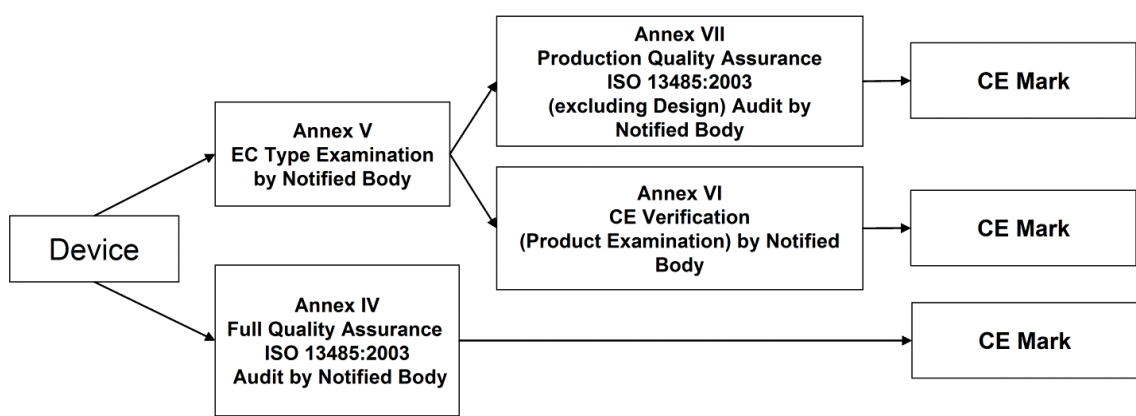
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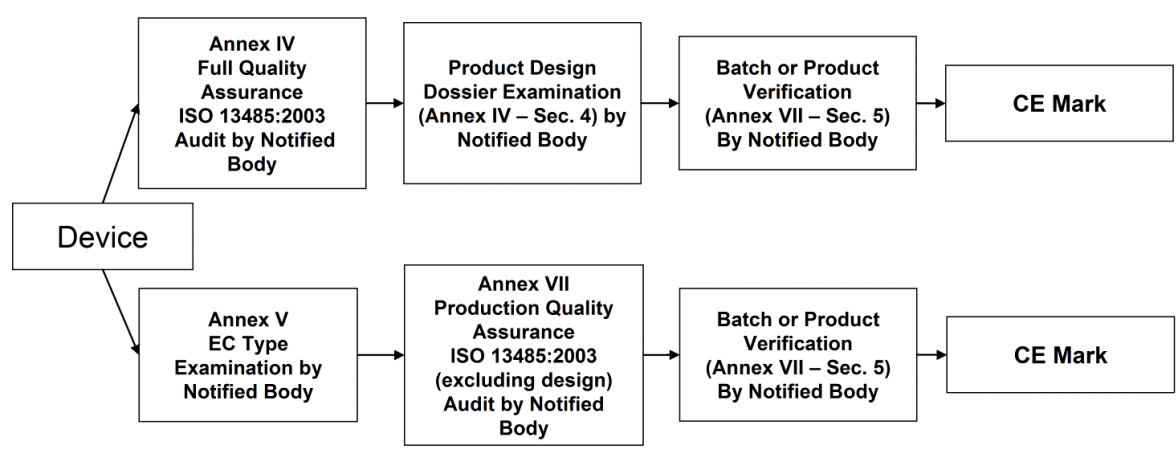
Self Testing IVD's (excluding those which appear in Annex II)



IVD's appearing in Annex II List B



IVD's appearing in Annex II List A



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