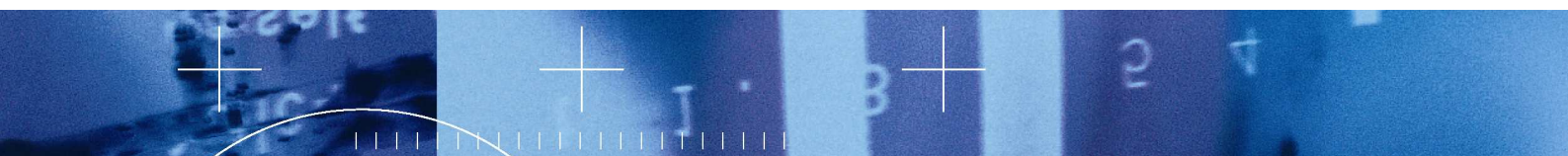


DGM Service

CE Marking of In Vitro Diagnostic Medical Devices



Background

The European Union has issued a directive 98/79/EC regulating *in vitro* diagnostic medical devices and requiring compliance to the directive to be demonstrated by CE marking the devices.

The transition period for *in vitro* diagnostic medical devices expired on December 7, 2003. After this date all *in vitro* diagnostic medical devices that are marketed in Europe must bear the CE marking.

The *in vitro* diagnostic medical device directive requires independent assessment of products and quality systems. For this purpose the member states have nominated a number of organizations, so-called Notified Bodies, to do third party assessments.

Danish Standards / DGM is the Danish Notified Body guiding manufacturers of IVDs quickly and efficiently through the CE marking process. DGM uses some of the most competent experts in the world within their field.

DGM offers

- Assistance in identifying most appropriate conformity assessment route
- Full quality system assessment (Annex IV of the Directive)
- Production quality assessment (Annex VII the Directive)
- EC type-examination (Annex V of the Directive)
- EC design-examination (Annex IV, section 4 of the Directive)
- EC verification (Annex VI of the Directive)
- Technical file evaluation
- Assessment of clinical data
- Assessment of labelling and IFUs
- EC certificate issue

Requirements for the Manufacturers

The natural or legal person responsible for the design and manufacture of the product and who markets the product in his own name is defined in the Directive as the manufacturer, regardless of whether these operations are carried out by himself or on his behalf by a third party. All the requirements in the Directive relate to the manufacturer when it comes to the products' ful-

fulfilment of the "Essential Requirements", preparation of technical documentation and risk analysis, clinical data, safe reproduction of the medical devices and incident reporting.

Conformity Assessment Routes

The Directive establishes different types of conformity assessment procedures. The principle is that the manufacturer can choose if he wishes to have his product and/or his quality system approved.

Notification – in vitro diagnostic medical devices:

Danish Standards / DGM has been notified by the Danish Ministry of the Interior and Health to approve in vitro diagnostic medical devices in accordance with Council Directive 98/79/EC.

For the following devices referred to in **list A** of Annex II tasks can be performed as described in Annexes IV, V and VII of Directive 98/79/EC:

- Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of **HIV infection (HIV I and II), hepatitis B, C and D, and HTLV I and II.**
- Reagents and reagent products, including related calibrators and control materials, for determining the following **blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell**
- Including self-testing devices variants of the above.

For the following devices referred to in **list B** of Annex II tasks can be performed as described in Annexes IV, V and VII of Directive 98/79/EC:

- Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: **Rubella and toxoplasmosis.**
- Reagents and reagent products, including related calibrators and control

materials, for determining the following human infections : **Cytomegalovirus.**

- Reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: **PSA.**
- Including self-testing devices variants of the above.

Further IVD self-testing devices other than those listed in Annex II can be approved by Danish Standards / DGM.

The notification in the field of IVD has been achieved in cooperation with the Paul-Ehrlich-Institut and Statens Serum Institut, which moreover make their expertise available to DGM.

More information

For more information about CE marking of in vitro diagnostic medical devices, please contact DGM at +45 39 96 64 00 or dgm@ds.dk.

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