

December 23, 2015

Cerilliant Certified Spiking Solutions[®] Why not CE marked?

Cerilliant Certified Spiking Solutions[®] are not CE marked because they do not meet the definition of an in vitro diagnostic device in the EU. Under the EU rules it would be illegal to CE mark any product not falling under the Directive. They are, however, critical starting materials suitable for use in the production of controls and calibrators and are manufactured under our ISO 13485 certification to fulfill the quality requirements for this potential use. Discussion of the relevant Guidance is below.

Cerilliant Certified Spiking Solutions[®] are Critical Starting Materials, not IVD

Cerilliant solution Certified Reference Materials / Certified Spiking Solutions[®] are designed for use as critical starting materials in the production of IVD controls and calibrators, either in laboratory or by a manufacturer. They are, however, **not used directly in vitro** and are at least one step removed from the criteria of an IVD. Article 1(2)(b) of the IVDD states (emphasis added):

*... 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, ...***

Cerilliant's products may be used to produce controls and calibrators, and the finished controls and calibrators may be subject to the Directive, but **not the raw materials from which they are made.**

No Stated Medical Purpose

In order for a product to be regarded as an IVD, it must first meet the definition of a medical device. A medical device must have a medical purpose. "Medical purpose" is not formally defined; however, MEDDEV 2.1/1 addresses medical purpose as (emphasis added):

*Medical devices are defined as articles which are intended to be used for a medical purpose. The medical purpose is assigned to a product by the manufacturer. The manufacturer determines, through the label, the instruction for use and the promotional material related to a given device its specific medical purpose. As the directive aims essentially at the protection of patients and users, the **medical purpose relates in general to finished products** regardless of whether they are intended to be used alone or in combination. **This means that the protection***



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ensured by the directive becomes valid for products having a stage of manufacture, where they are supplied to the final user.

Following this concept, raw materials, components or intermediate products are normally not medical devices. Such raw materials may need to present properties or characteristics which are determinant for the safety and quality of finished devices. It is therefore the responsibility of the manufacturer of finished devices to select and control by adequate means his raw materials or intermediate products

The above makes very clear the intent to exclude raw materials from the scope of the directive. It also states that those manufacturing controls and calibrators for IVD use, in lab or as a commercial endeavor, must consider and control the quality of raw materials. (see also "Cerilliant Certification to ISO 13485" below)

In addition, borderline issues concerning IVDs are addressed by MEDDEV 2.14/1, Rev.2. Of particular relevance are sections 1.4 and 1.7 addressing general laboratory equipment and control materials. Section 1.4 addresses the distinction between an IVD and general laboratory equipment and indicates a fairly stringent requirement for products to be intended for a specific test in order to meet the definition of an IVD.

Although this section includes stand-alone calibrators/controls, as discussed above, the Cerilliant Certified Spiking Solutions® are not in themselves calibrators/controls, but starting materials for the end-user to produce controls and calibrators. Thus, the products are not brought under IVD regulation by this section.

The guidance indicates that Cerilliant solution Certified Reference Material /Certified Spiking Solutions® do not meet the definition of an IVD in the EU and cannot be CE Marked to the IVD Directive.

Laboratory Exemption

Article 1(5) of the IVDD exempts "in-house tests," (AKA "home brew tests" or "Laboratory Developed Tests "LDTs") which are considered "devices manufactured and used within the same healthcare institution and on the premises of their manufacture..." Thus, even end-users who are using Cerilliant Certified Spiking Solutions® to develop tests for use within their healthcare institution would not be subject to the IVDD.



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Cerilliant Certification to ISO 13485

As noted above, the guidance makes very clear that those manufacturing controls and calibrators for IVD use, in lab or as a commercial endeavor, **must consider and control the quality of raw materials**. As discussed, Cerilliant Certified Spiking Solutions[®] are considered raw materials under the guidance. **Cerilliant Certified Spiking Solutions[®] are designed and manufactured with this critical end-use in mind**. Cerilliant maintains certification to ISO 13485 and ISO 9001 and accreditations to ISO Guide 34 and ISO 17025 to provide assurance that Cerilliant products are designed, manufactured, and tested to the highest quality standards and to help laboratories and manufacturers meet their stringent quality needs and regulatory requirements.

Regards,

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