

Progress Report September 2010

LNE/G-MED: Sharing a Passion for Progress

Are Changes Coming to the IVD Directive? Europe Commission Initiates “Public Consultation”

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The European classification of IVD Medical Devices under Directive 98/79/EC faces criticism for being seen as rigid and unable to address new technologies or practices. Could a change in the rules be coming?

The European Commission has launched a “public consultation” on the In Vitro Diagnostic Directive (IVDD), which has been in place since 2003. LNE/G-MED participated with other notified bodies in a joint response. We invite you to **submit your opinion by the deadline of September 15, 2010**. Details at: http://ec.europa.eu/consumers/dyna/newsroom/itemlongdetail_en.cfm?item_id=25&tpa=164&type_id=5.

The enclosed newsletter explains the current IVD assessments procedures, examines the approach taken by the Global Harmonization Task Force (GHTF) and identifies the other IVD elements under review.

Current IVD Assessment Procedure

Under the In Vitro Diagnostic Directive (IVDD), medical devices are categorized based on whether they are specifically listed in Annex II of the directive (list A for the most risky devices, list B for lower risk devices) and whether they are intended for self-testing.

Devices fall into one of the following categories:

- List A devices are of particular importance for blood transfusion or graft transplantation.
- List B devices present a lower level of risk but still relate to the diagnostic of critical pathologies or state of health and must demonstrate their sensitivity, specificity and other attributes related to reliability.
- Self Testing devices deserve particular attention because of the higher potential of misuse, misinterpretation of the test result or test failures with significant impact on the medical decision that the test result may lead to.
- An Other category covers devices that don't fit into any of the above groups.

See the chart on page 3, which summarizes the current CE Marking assessment routes that a manufacturer may chose, depending on the status of its IVD medical device.

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Pros & Cons of Europe's Approach Compared to Others

The main benefit of using explicit listings is the clarity of the process. Either the device is clearly listed or it falls under the "others" category. With limited room for interpretation, the system tends to be straightforward and convenient.

The U.S. regulation, which also uses lists, prescribes a more comprehensive listing of over 1,000 product codes, with specific product types being assigned based on risk to Class I, II or III.

Critics of the Directive 98/79/EC classification system point out the perceived arbitrary nature as to whether something is listed or not, along with the inability to effectively address new technologies.

An approach based on classification rules, related to intended use and other critical attributes, gives more flexibility with regards to new technologies. (See details of GHTF system in sidebar.)

The downside of the classification rule approach is the difficulty of covering all devices in an unambiguous way.

Other IVDD Issues Under Review

The public consultation also addresses other topics related to Directive 98/79/EC, including:

- **Conformity Assessment:**
Should the current assessment routes be modified with the adoption of an IVD classification system?
- **Scope:**
Should "in-house test" remain excluded from the scope of the revised IVD directive?
Should the scope be clarified regarding genetic tests, diagnostic services performed by the manufacturers themselves or near-patient in vitro diagnostic medical devices?
- **Clinical Evidence:**
Should the directive be clarified in terms of demonstration of performance, clinical validity and clinical utility?
- **Conditional CE Marking:**
Are there some situations such that the implementation of the current rules might prevent the rapid access of a product on the market despite an actual need?

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Another IVD Option: GHTF Classification

One possibility for European classification of IVDs is to adopt Global Harmonization Task Force (GHTF) rules, to further harmonize rules and possibly strengthen standards.

Australia adopted this system this year, China did so in 2009 and Canada has been using a similar approach since 1998.

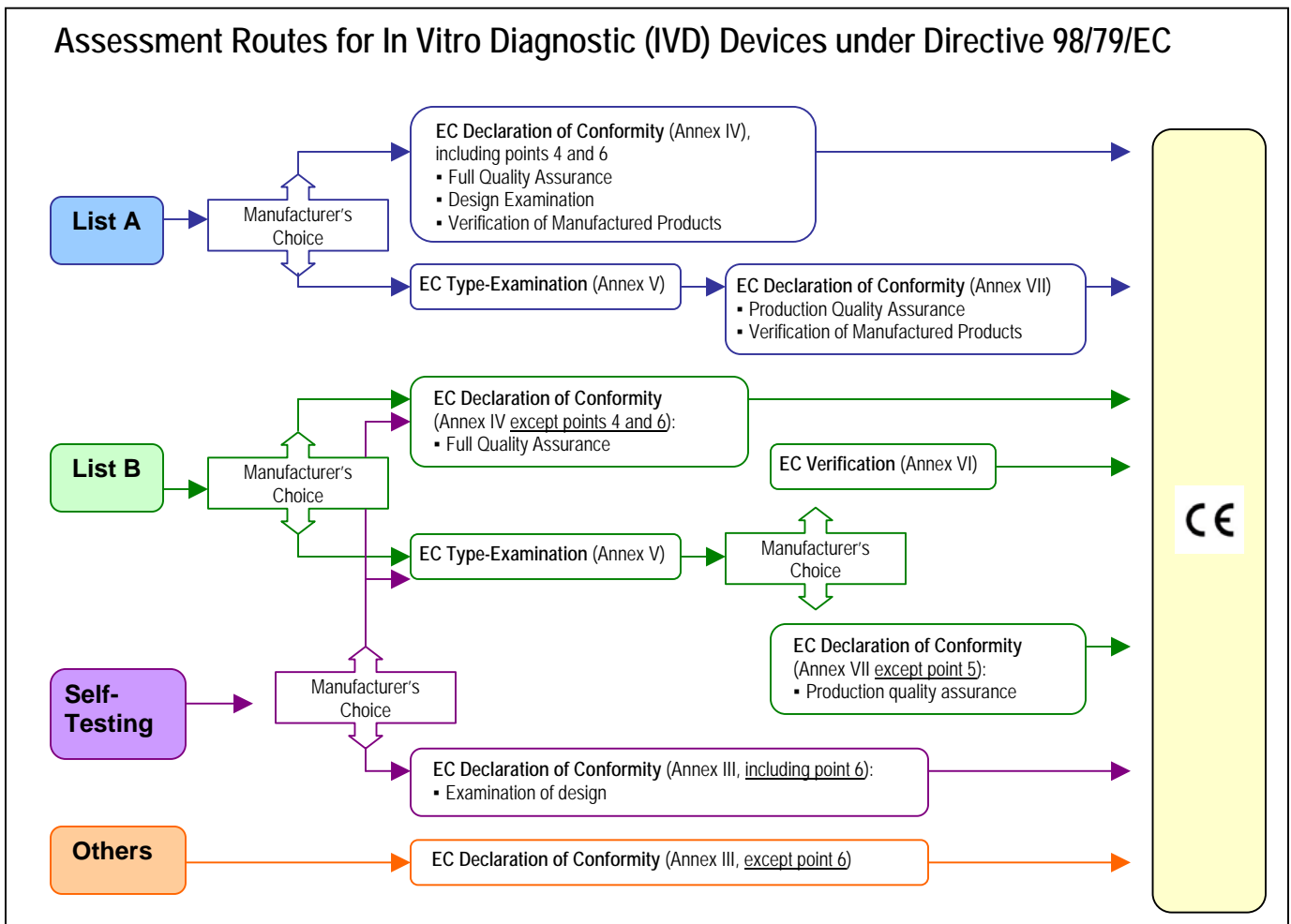
The GHTF classification system is based on the evaluation of risk taking into account the:

- intended use and indications for use as specified by the manufacturer (including the pathology)
- knowledge of user (clinical lab, patient)
- significance of the result in the medical decision making process
- impact of a false diagnosis.

GHTF could improve the robustness of the EU IVD regulation and public safety by requiring more IVD devices to complete an assessment by a notified body. It categorizes IVD products by rule into four classes, with risk level increasing from A to D:

- Rule 1 (Class D): Tests for blood, tissue, organ screening prior to transfusion, transplantation.
- Rule 2 (Class C or D): Tests of immunological compatibility, classified by their criticality.
- Rule 3 (Class C): Devices presenting a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis.
- Rule 4 (Class B or C): Self-testing devices, classified by their criticality.
- Rule 5 (Class A): IVD reagents, instruments and test receptacles.
- Rule 6 (Class B): Applies to all other devices.
- Rule 7 (Class B): IVD controls without a quantitative or qualitative assigned value.

- **Companion in vitro medical devices:**
Does the regulation appropriately address the quality of IVD tests specifically intended for use in combination with drugs?



Technical Questions? Ask our experts here: <http://www.lne-america.com/quality-news-faqs/ask-our-experts.html> to get clear answers or be directed to the proper resources. Or call us at (301) 495-0477.

FREE Webinar: *Selling Medical Devices in Europe*: Get answers to your questions on CE Marking and Notified Body services directly from our technical experts. After a short presentation on the EU Directives, essential requirements and other key topics, our expert opens the discussion to address your specific questions.

The seminar is on Wednesday, September 29; 2:00 – 3:00 p.m. (EST). **Register FREE** by emailing your contact information to training@lne-gmed.com. Be sure to include a question for our speaker. Space is limited so reserve your spot today.

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