



Product Service

Choose certainty.  
Add value.

## Med-Info

International expert information  
for the medical device industry

# Recent and ongoing changes to the European regulation of in-vitro diagnostic (IVD) medical devices

### The current regulatory framework for IVDs is going to be revised

The current regulatory framework for the handling of in-vitro diagnostic (IVD) medical devices in the EU is about to be repealed and replaced.

Directive 98/79/EC on in-vitro diagnostic medical devices, which the member states have transposed into national law through national legal acts such as the German Medical Devices Act, has been mandatory for more than ten years. Throughout this period only a few amendments have been made, such as the extension of the scope of the Directive by adding vCJD assays for blood screening.

The legal framework conditions for in-vitro diagnostic medical devices are currently undergoing major changes, some of them already effective, which will result in a complete revision of the regulatory framework and the publication of an EU regulation on in-vitro diagnostic medical devices in a period of time not yet foreseeable with any precision. Parallel to this process, the European legislation for medical devices will also be changed accordingly.

In spite of the justified criticism concerning the current regulatory framework for IVDs, the application of the Directive has achieved a relatively high level of quality for IVDs and medical devices within the EU.

### What is the motivation behind the changes?

There is a number of reasons necessitating a revision of the regulatory framework, the most important from the author's point of view being:

- An update and revision of the Directive to make it more flexible has been planned for some time.
- The EU member states interpret and implement the current rules in different ways.
- Market conditions have changed and new products, e.g. diagnostic services, are being developed.
- There are discrepancies with regard to regulations and rules developed in the meantime governing IVDs on international level.
- Various scandals related to medical devices have brought market supervision and the work of Notified Bodies in charge of the assessment of medical devices to the attention of the public.

The last aspect in particular is characterized by special dynamism which, in turn, triggered additional actions that will be addressed further below.

### Preparation for the revision of the legislation

The impending revisions were initiated by the European Commission which launched a **public consultation** in Summer 2010 to seek the views of stakeholders on 19 items concerning IVD regulations, including risk-based classification, obligatory assessment of the quality management system of manufacturers, exemptions for devices manufactured and used only within the same health institution („in-house tests“), genetic tests, tests and testing services offered to lay persons, and companion diagnostics. This already illustrates some of the items for which new regulations were expected. Interested parties were given ten weeks (up to September 15, 2010) to respond to these questions. The evaluation of the consultation was published on February 23, 2011, followed by a period of apparent calm.

Finally, on September 23, 2012, the **European Commission Proposal** for a regulation on in-vitro diagnostic medical devices – **COM(2012) 541 final** – was published at the same time as the proposal for a regulation on medical devices.

This was the starting point for public and parliamentary discussion which shall result in a text for the future IVD Regulation agreed by EU Commission, EU Parliament, and the Council of the European Union.

The EU Commission Proposal initiates a fundamental change in the European legislative framework for in-vitro diagnostic medical devices: In contrast to the requirements of the IVD Directives which still had to be transposed into national law by the EU member states, the rules of the IVD Regulation will become effective immediately throughout all EU member states without requiring transposition into national law, thus resulting in fewer national regulations as the minimum effect.

While many changes will specifically apply to in-vitro diagnostic medical devices, others will apply equally to both medical devices and IVDs. The upcoming changes for in-vitro diagnostic medical devices will be very far-reaching, particularly because of the new risk-based classification of medical devices.

### **The Commission Proposal for a regulation on in-vitro diagnostic medical devices**

The EU Commission's proposal includes a multitude of changes that can only be touched upon very briefly in this information leaflet. The changes concern the following aspects:

- Scope of the devices affected
  - Diagnostic services, distance (Internet-based) diagnostic services, companion diagnostics, genetic tests
  - In-house manufacturing – restriction of the exemption existing under IVDD Article 1 (5) to devices in classes ABC that are manufactured and used exclusively under the health institution's single quality management system (care, treatment, or promotion of public health), provided the health institution is compliant with the ISO 15189 standard or a similar standard recognized as equivalent
- Introduction of new/innovative roles and responsibilities
  - Rules for the supply chain (supply chain, importers, distributors)
  - Commission: authorization to issue implementing acts
  - Medical Device Coordination Group (MDCG) (comprising experts appointed by the member states)

- to harmonize the interpretation and procedure
- Reference laboratories to verify compliance of class D devices with the applicable Common Technical Specifications (CTS), carry out tests on samples and batches of class D devices, provide scientific advice on the state of the art, etc.
- More stringent criteria for the designation and monitoring of Notified Bodies
- Change of classification to a risk-rule-based classification system build on the principles developed by Global Harmonisation Task Force (GHTF) and providing for the classification of IVDs into four classes (A to D) according to their risk potential. Even though the classification rules still require further clarification, we expect to see a significant rise in the number of devices assigned to the second highest class (C). Given this, the number of devices that must undergo conformity assessment with the involvement of a Notified Body will increase considerably.
- Conformity assessment procedures
  - Assessment of the manufacturer's quality management system mandatory from class B upwards
  - Scrutiny mechanism for class D medical devices: selective monitoring of assessment by the MDCG
  - Special procedure for class A medical devices with a measuring function, Point-of-Care (POC) devices and sterile devices
  - Introduction of procedures for companion diagnostics including the obligation to consult a competent authority in the field of medicinal products.
  - Additional conformity assessment procedure to enable parallel imports
  - Abolition of EC verification
- Functioning of Notified Bodies
  - Unannounced audits
  - Examination of device samples also taken from the market
  - Regular change of the auditor team
- Product-related requirements (frequently concerning clarification)
  - Essential requirements
  - Technical documentation
  - Clinical trials
- Introduction of a (qualified) person responsible for regulatory compliance and/or an EU representative (Article 13)
- Unique Device Identification (UDI) – Introduction of a system to ensure the identification and traceability of devices (UDI System)
- ...

## Further requirements of the EU Parliament

In its first reading, which was completed April 02, 2014, the EU Parliament called for significantly stricter requirements compared to those in the Commission Proposal, e.g.:

- Establishment of special Notified Bodies for future class D products (notified with the involvement of the European Medicines Agency, EMA)
- Generally stricter requirements for the qualification and supervision of Notified Bodies
- Additional establishment of an Assessment Committee for Medical Devices (ACMD)
- Replacement of the scrutiny mechanism with case-by-case assessment by the ACMD
- Further-reaching duties of disclosure, particularly for manufacturers and Notified Bodies
- Shortening of the transition period to three years
- Increase of the level of detail of the specifications

## Further requirements of the Council of the EU

After laborious negotiations the Council published its preliminary position on June 19, 2015, covering all articles and annexes of the proposal of the Commission except the preamble. The changes called for by the Council primarily focus on the UDI system, the European database, the Notified Bodies, clinical effectiveness/performance characteristics, after-sales product surveillance, vigilance and interaction of competent authorities, and go into detail. Further major changes are:

- Materials for Round Robin/proficiency testing are to be exempted from the provisions of the Regulation.
- The definition of companion diagnostic devices is to be expanded.
- The rules for reagents produced in health-institution laboratories are to be formulated more precisely.
- Manufacturers must undertake to implement a full quality management system.
- The EU Representative is to take legal responsibility for faulty products.
- A “qualified person” must also be available with the EU Representative.
- A scrutiny procedure is only to be initiated after certification of a Class D product in case considered necessary.
- Class A devices for near-patient testing or with measurement functions are not to be subject to evaluation by Notified Bodies.
- All devices for self-testing to be classified as Class C.

In contrast to the Parliament, the Council has adopted the Commission’s proposal of a five-year transitional period and does not demand “Special Notified Bodies”. The Council has meanwhile completed and endorsed his position.

## Status of the legislative process

The process so far and the next steps in the legislation procedure are listed below:

- September 23, 2012: Commission Proposal
- April 2, 2014: first reading of the European Parliament completed
- June 19, 2015: Preliminary statement of the Council on the Commission Proposal
- October 5, 2015: Council endorsed its position as fixed in the document issued September 21, 2015, by the Permanent Representatives Committee
- starting from October 15, 2015: Talks between Parliament, Council and Commission (Trilog) with the objective to achieve early agreement within 2nd reading.

A glance at the **general legislative procedure of the EU** outlined in **Article 294 of the Treaty on the Functioning of the European Union** shows that the further process is subject to strict time lines:

- Commission Proposal
- First reading (no time limit)
  - Parliament’s position (available)
  - Council position (available)
- Second reading
  - Within three months of the communication of the Council’s position: EP expresses its position.
  - Within three months of receiving the EP’s amendments, the Council approves the amendments or convenes a meeting of the Conciliation Committee within six weeks (the Council shall act unanimously regarding the amendments on which the Commission has delivered a negative opinion).
  - The Conciliation Committee, comprising members of the EP and the Council, must agree on a joint text within six weeks of being convened.
- Third reading
  - Within six weeks after approval of a joint text by the Conciliation Committee: approval and adoption by Council and EP

The periods mentioned above can be extended from three to four months and from six to eight weeks respectively.

Owing to the complexity of the subject, the deadlines, and the time needed for documentation, the author expects completion of the legislative procedure approximately mid of 2016, provided the procedure is not terminated prematurely.

### Further measures taken by the Commission – joint action plan

In awareness of the length of legislative procedures and triggered by the scandal caused by fraudulent breast implants (PIP) as well as the problems related to hip implants, the Commission, in consultation with the Council, passed a **joint action plan under the existing medical device legislation**, also called „Dalli Action Plan“ in reference to the then acting EU Health Commissioner.

The actions concern the Commission, the member states, and Notified Bodies, and target:

- Function of Notified Bodies
  - Stricter rules for the designation of Notified Bodies
  - Re-assessment of Notified Bodies that evaluate devices in the highest risk class
  - Clarification of the responsibilities of the Notified Bodies
  - Provision of vigilance information to the Notified Bodies
- Strengthening of market surveillance by the member states
- Improvement of the coordination of activities by the member states
- More transparency and improved communication of incidents

In view of these developments a „Code of Conduct“, defining a standard for the qualification of personnel and the conduct of assessment, and ensuring independent verification, was agreed, originally by five Notified Bodies including TÜV SÜD Product Service.

To facilitate implementation of the planned actions, the Commission published the following three documents:

- **Commission Implementing Regulation 920/2013/EU** of September 24, 2013, on the designation and supervision of Notified Bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (even though the scope of this Regulation does not include

the IVD Directive, the Regulation is expected to impact on the Notified Bodies for IVDs which mostly form part of the Notified Bodies for medical devices)

- **Commission Recommendation 2013/473/EU** of September 24, 2013 on the audits and assessments performed by Notified Bodies in the field of medical devices
- **Commission Recommendation 2013/172/EU** of April 5, 2013 on a common framework for a unique device identification system of medical devices in the Union. This recommendation facilitates the establishment of a UDI system.

The requirements defined in these documents, in particular the requirements concerning the Notified Bodies and their activities, anticipate some of the provisions expected in the IVD Regulation. The implementing regulation and the recommendation on audits and assessments will be addressed in greater detail below.

**Implementing Regulation 920/2013/EU** includes detailed provisions governing the designation and supervision of the Notified Bodies. It came into effect on October 15, 2013, for extensions of designations on December 25, 2013.

Key changes include the assessment of Notified Bodies by joint audit teams with the involvement of representatives of authorities from other member states and the Commission, and the Commission's right to overrule decisions by the national designating authorities of the member states.

**Commission Recommendation 2013/473/EU** on the audits and assessments performed by Notified Bodies in the field of medical devices is currently being implemented and concerns product assessment, assessment of the quality system, and unannounced audits. According to the Commission, „this recommendation does not create any new rights and obligations“, even though some of the stakeholders do not agree with this statement. However, many stakeholders are actually asking whether a recommendation can have binding character.

Even though the title of the document does not sound like an obligation, the recommendation has binding character as the member states are called upon „to supervise the practice of the Notified Bodies with respect to this recommendation“ and consider it in designations and extension of designations.

While this recommendation does not include any major changes in product assessment in the author's opinion, it defines new focuses for the assessment of the quality assurance system. These focuses primarily aim at tracking **the quantities of crucial raw materials**, in cases where their replacement may result in risks, **and monitoring of the supply chain** and the legal manufacturer's obligations associated therewith.

**Unannounced audits** have become obligatory in addition to initial, surveillance, or re-certification audits, and must be carried out once every three years including critical subcontractors and crucial suppliers if necessary. Unannounced audits should be carried out by two auditors and take at least one day. They should focus on the conformity of a sample taken from ongoing manufacturing processes with the technical documentation and the legal requirements, as well as on traceability. In addition, in-depth testing of at least two critical work processes is required. If necessary, the Notified Body should undertake a test in accordance with the testing procedures defined by the manufacturer in the technical documentation to determine conformity; the test may also be performed by the manufacturer, its critical subcontractor, or crucial supplier under observation of the Notified Body. For products with an existing product assessment, testing by the Notified Body of samples of these products taken from ongoing production is obligatory.

Notified Bodies have meanwhile started to carry out unannounced audits.

Further information:

<http://www.tuv-sud.com/unannouncedaudits>

## Final note

The IVD Regulation will bring major changes, even though the details have not yet been agreed and the date when these changes will come into effect as well as the transition periods are still open. Some ideas of the EU Parliament go far beyond the Commission's Proposal; the changes requested by the Council are numerous and in several cases very detailed. Some of the requirements of the proposed IVD Regulation have already been implemented by other legal means and will come into effect shortly, if not already effective yet. One thing is certain: The costs and the efforts required to reach and supervise "Regulatory Compliance" will increase noticeably for all stakeholders – manufacturers, Notified Bodies, and authorities.

**Your contact partner at TÜV SÜD Product Service can provide further information.**

Dr. Dieter Schönwald

Phone: +49 89 5008-4241

Email: [dieter.schoenwald@tuev-sued.de](mailto:dieter.schoenwald@tuev-sued.de)