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Directive 98/79/EC on In Vitro Diagnostic Medical Devices 欧盟体外诊断医疗器械 指令(IVDD)

TÜV SÜD Group

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In vitro diagnostic medical devices are subject to the European Directive 98/79/EC (IVDD). As a subgroup of medical products, their market access, use, and market surveillance is regulated. The Directive is implemented in the national laws of the member states.

What are in vitro diagnostic medical devices (IVDs)?

According to the Directive, in vitro diagnostic medical devices include: reagents, reagent products, calibration materials, control materials, kits, instruments, apparatus, equipment, and systems that are intended for use in the examination of specimens taken from the human body to diagnose diseases, to monitor a person's physiological state, or to monitor therapeutic procedures.

Examples of in vitro diagnostic medical devices are:

- Hepatitis or HIV tests
- Clinical chemical tests
- Coagulation test systems
- Urine test strips
- Pregnancy tests
- Blood sugar monitoring systems for diabetics
- Receptacles manufactured specifically for medical specimens

Devices for self-testing

Devices for self-testing form a special IVD group. These IVDs are intended by the manufacturer to be used by laypersons in a home environment, for example pregnancy tests.

体外诊断医疗设备属于欧盟指令98/79/EC (IVDD) 的范畴。在该指令下，医疗产品子群的市场准入、使用和市场监管已得到规范。该指令已在欧盟成员国的国家法律中实施。

什么是体外诊断医疗器械？

IVDD指令明确界定，体外诊断医疗器械是指以疾病诊断、治疗或病程监测为目的，用来对采集自人体的标本进行检测的医疗器械、包括试剂、校准品、质控品、试剂盒、仪器、设备、部件及系统。

例如：

- 艾滋病诊断试剂盒
- 临床化学试剂
- 凝血诊断系统
- 尿液测试条
- 早孕试纸条
- 血糖仪
- 检测标本专用容器

自我测试器械

自我测试器械是体外诊断器械的一个大类。生产商规定其预期使用对象是未接受过专业医学教育的非专业人员。例如供用户在家中使用的早早孕试纸条就是一种自我测试器械。



Devices for performance evaluation

Devices to be used in performance evaluation studies outside of the manufacturer's facility are also covered by the Directive.

Exceptions:

Products that are used only for veterinary medicine as well as products for general laboratory use are not subject to the IVD Directive.

However, sampling devices that are either invasive or come into contact with patients are subject to Directive 93/42/EEC on medical devices.

Who is the manufacturer according to the directive?

The Directive defines the manufacturer as the natural/legal person who is responsible for the design, manufacture, packaging, and labelling of a finished device for the purpose of marketing under his/her own name, regardless of whether these activities are performed by that person or by a third party acting on his/her behalf.

Manufacturers of finished IVD products outside the EU must have a representative within the EU.

Essential requirements for in vitro diagnostic medical devices:

Annex I of the Directive requires that the safety and health of patients, users, and any third party must not be endangered by proper use of the product and that any possible product risk – compared with the associated benefit – is acceptable.

性能评价器械

性能评价器械是体外诊断器械的一个大类，例如用于医学实验室考核的室间质控品。其也在本指令管辖范围之内。

不属于体外诊断医疗器械的产品：

专门用于兽医领域的器械和实验室通用器械并不在本指令定义的体外诊断医疗器械范围之内。

那些采用侵入的方式获取人体标本的器械则属于Directive 93/42/EEC 管辖的范畴。

谁是指令所规定的生产商？

指令所定义的生产商可以是法人，也可以是自然人。生产商以自己的名义将产品上市，并对产品的设计、生产、包装、标签承担责任，无论这些过程是其自己完成的还是委托第三方完成的。如果生产商在欧盟境外的，则其必须在欧盟境内有其指定代表。

体外诊断医疗器械的基本要求：

指令附录一规定：病人、使用者及其他相关人员的健康与安全必须得到保障；产品可能的风险与其益处相比应在可接受范围之内。为此，产品的设计与生产方案必须确保安全，应采取措施避免或降低风险。



Other requirements that apply to the design and manufacture of IVD products:

- chemical and physical characteristics (compatibility with the material to be tested)
- protection against infection and microbial contamination (processing, packaging)
- suitability for use under the respective environmental conditions (risk minimization)
- combination with other products, disposal
- measurement function
- protection against radiation (intentional or non-intentional radiation, ionizing radiation)
- protection against electrical shocks, electromagnetic compatibility
- protection against mechanical or thermal risks
- use by laypersons: easy to use, low risk of incorrect interpretation of results (products for self-testing only)
- provision of information by the manufacturer (labelling, instructions)

Annex III: Manufacturer's Self-Declaration

The manufacturer must compile and maintain a technical documentation showing that the product meets the applicable requirements. The manufacturing process must comply with the principles of quality assurance. A system for market surveillance, reporting, document storage, etc. must be in place. After successful self-assessment without participation of a Notified Body the manufacturer issues a declaration of conformity.

除了通用的要求外，对体外诊断器械的设计与生产还有下列特殊要求：

- 器械的化学和物理性质与被测标本相容
- 在生产、包装过程中避免微生物污染或员工感染
- 环境要求（应将风险最小化）
- 与其他器械结合使用的问题
- 定量功能
- 辐射防护（包括在离子型和非离子型辐射中的正常暴露和意外暴露）
- 外部或内部的能量输入（例如电击防护问题，电磁兼容性问题）
- 机械或热力的防护
- 非专业人员用器械的附加要求：操作简单、风险等级较低
- 标签与说明书

Annex III: 制造商的自我声明

该途径规定生产商在没有公告机构参与的情况下自行发布符合性声明。生产商应建立一套技术文件，证明器械符合IVDD指令及相关欧盟标准的要求。同时，整个生产过程应满足质量保证的要求。相关的市场监督系统、事故报告程序、文件保存要求等也应自行建立。



Annex IV: Full Quality Assurance System

The manufacturer has a full quality management system (ISO 13485 including design), fulfils the additional requirements of the Directive (e. g. Annex I), and declares the conformity of his products with the Directive. These measures are assessed in initial and surveillance audits by a Notified Body. In addition, List A devices require a product design examination according to Annex IV.4 and verification of manufactured products according to Annex IV.6 by the Notified Body, focussing on lot-to-lot consistency.

Annex V: EC Type-Examination

A Notified Body conducts a type evaluation to check the compliance of the prototype with the essential requirements of Annex I of the Directive and issues a type examination certificate.

Annex VI: EC Verification

A Notified Body tests the finished products. Each product batch is tested and released individually.

Annex VII: Production Quality Assurance

The manufacturer has a quality management system for production, testing, and final inspection (ISO 13485) and meets the additional requirements of the Directive (Annex I).

Annex IV: 完整的质量管理体系

该途径要求生产商建立一个涵盖设计控制过程的、完整的质量管理体系（如 ISO13485），并同时满足IVDD指令的附加要求（如市场监督、事故报告、文件保存等）。产品的安全性和有效性应满足IVDD指令Annex I 中适用条款的要求。生产商应声明产品符合IVDD指令及相关欧盟标准的要求。对于List A 范围内的产品，还有附加的设计文档审查和批检要求。该认证途径必须由公告机构参与。

Annex V: EC 型式测试

由公告机构对生产商提供的器械进行测试评估，确认器械是否满足IVDD指令Annex I 的要求，并颁发型式试验证书。

Annex VI: EC 查证

由公告机构对生产商生产的成品进行测试。每批产品都必须接受检测并放行。

Annex VII: 产品质量保证

该途径要求生产商建立一个涵盖生产、测试和成品检验过程的质量管理体系，并同时满足IVDD指令Annex I 的附加要求。



Product Groups:

The Directive distinguishes four different groups – based on the risk associated with the use of the respective products.

List A

List A of Annex II contains the products with the highest potential risk. These include reagents,

- calibrators and controls for the determination of blood groups (ABO system, rhesus, and anti-Kell)
- HIV-1/-2 infections, HTLV-I/-II infections, and hepatitis B, C, and D.

List B

List B of Annex II contains high risk products (reagents, calibrators and controls unless otherwise stated):

- for the determination of blood groups (anti-Duffy and anti-Kidd)
- for determination of irregular anti-erythrocyte antibodies
- for the detection of rubella and toxoplasmosis
- for the diagnosis of phenylketonuria
- for the detection of infections with cytomegalo virus or Chlamydia
- for the determination of the tumour marker PSA
- for the determination of HLA tissue types DR, A, B
- for the evaluation of the risk of trisomy21, including software
- products for self-testing of blood sugar levels Including instruments

产品分类:

IVDD 指令根据产品的风险及预期用途，在Annex II 中将体外诊断器械分成四类：

List A

List A 是具有最高潜在风险的产品，它包括：

- 血型分类试剂（ABO、rhesus 和anti-Kell 分类系统）
- HIV、HTLV-I/-II 和乙型肝炎、丙型肝炎、丁型肝炎诊断试剂

List B

List B 是具有较高潜在风险的产品，它包括：

- 血型分类试剂（anti-Duffy 和anti-Kidd 分类系统）
- Irregular anti-erythrocyte antibody 诊断试剂
- 风疹和弓形虫诊断试剂
- 苯丙酮酸尿症诊断试剂
- 巨细胞病毒和衣原体诊断试剂
- 前列腺特异蛋白诊断试剂
- 人类白细胞抗原诊断试剂（HLA DR, A, B）
- 21 对三联染色体风险检测试剂与软件
- 非专业人员用血糖监测系统



Devices for Self-Testing:

These are subject to special requirements, which are described in Annex I, Section 7 of the Directive:

- The product must be easy to use for laypersons, and the enclosed instructions must be easy to understand
- The risk of errors in use or in the interpretation of results must be kept as low as possible
- Where possible, such devices must include a user control which allows verification of correct performance at the time of use

自行检测指令:

供病人、家属等非专业人员使用的诊断器械（血糖除外）。IVDD Annex I 第7条规定:

- 该产品必须易于使用的，说明书应是易于理解的
- 错误操作带来的风险应尽可能控制在低水平
- 可能的话，使用者应可以通过适当方法确认器械使用过程是否正确有效

Other IVD Medical Devices:

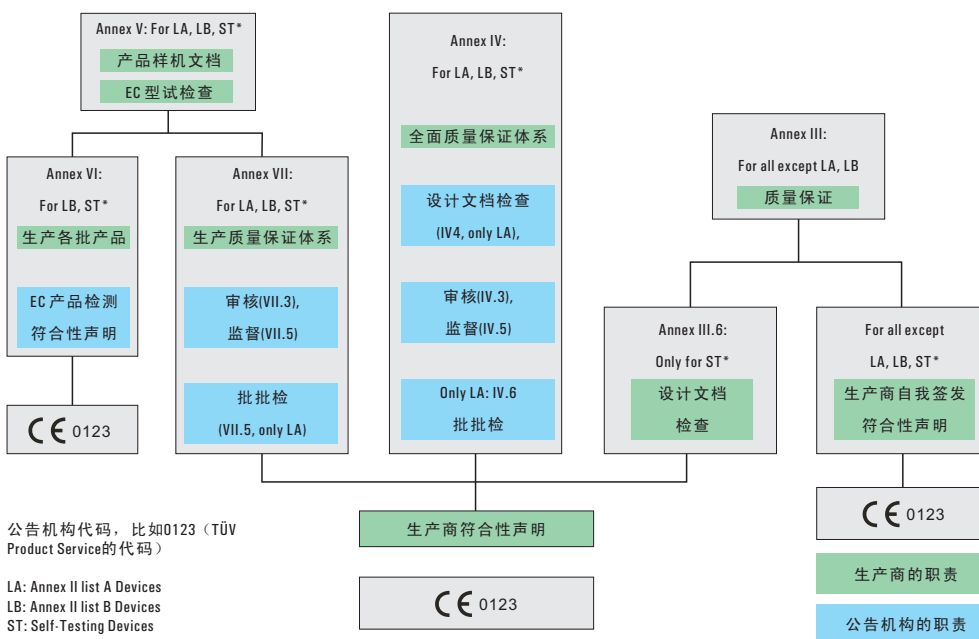
Products that are neither listed in Annex II nor intended for self-testing.

See the following figure for different conformity assessment route:

其他IVD医疗指令

IVDD Annex II 所列器械以外的且不供非专业人员使用的诊断器械。

不同产品的认证途径见下图:





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Among the above-mentioned approaches, Annex IV is the most commonly used one, applicable for all List A, List B and self-testing products. The two-step combination of design dossier and on-site audit is used for List A products, and only on-site auditing for List B and self-testing products. As for manufacturers choosing Annex IV certification approach, their QMS should conform to the requirements of ISO13485: 2003 and covers the design control process.

上述认证途径中, Annex IV是最常用的认证途径, 其适合与所有List A、List B和self-testing类产品。List A产品采用设计文档检查+ 现场审核的两步走模式。List B和self-testing类产品采用现场审核一步模式。对于生产型企业, 选择Annex IV的认证途径时, 其质量管理体系应当符合ISO13485:2003要求, 并且体系覆盖设计控制过程。

IVDD-related European Standards:

IVDD 相关欧洲标准:

| | | |
|-------------------|----------------------------|--------------------------|
| EN ISO18113系列 | EN ISO15197: 2003/ AC:2005 | EN ISO15193: 2009 |
| EN ISO15194: 2009 | EN 13532: 2002 | EN 12322: 1999 / A1:2001 |
| EN 13612: 2002 | EN 13640: 2002 | EN 13641: 2002 |
| EN 13975:2003 | EN 61010-2-101: 2002 | EN 14820:2004 |
| EN 14254:2004 | EN 62304: 2006 | EN 61326-2-6:2006 |

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