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et de la Mécanique  
de Précision

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Federation of  
Precision  
Mechanical and  
Optical Industries

Europäische  
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Feinmechanik  
und Optik

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## EUROM VI "Medical Technology"

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Enhancing the health of the public European wide and world wide and  
Facilitating innovation by harmonising the European and global regulatory environment

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# EUROM VI Medical Technology Comments

## on DRAFT Vademecum Part I to III

**EUROM VI Medical Technology** is the committee for Medical Technology within the European Federation of Precision Mechanical and Optical Industries and represents mainly European small and medium-sized enterprises.

The objectives of EUROM VI are:

- to represent European Medical Technology Industry;
- to promote cooperation between members but also with other European organisations;
- to encourage worldwide trade by being involved in harmonisation of legislation, standardisation, mutual recognition and certification procedures;
- to be a partner on works with the European Commission and Standardisation Bodies;
- to support European Industry views on international activities.



## EUROM VI Medical Technology Comments on DRAFT Vademecum Part I to III

### General comment:

The content of the *Draft Vademecum* (and the recently published *Guidance Note on European Standardisation 2015*) displays a basic misconception of the tool of standardization and the role of the European Commission in the European standardization system. European standardization is primarily a privately organized initiative. Some 90 to 95% of work on European Standards is initiated, supported and funded by industry or other private stakeholders. The regulator makes use of the tool of standardization by drawing from the technical expertise of its experts and thereby unburdening public authorities from detailed technical work. Within the framework of the New Approach and New Legislative Framework, harmonized standards give technical details whose application helps to comply to European regulation. Some principles of the system need to be remembered:

- Application of a harmonized standard is but one possibility to comply with a directive.
- Application of a harmonized standard means that it can be presumed that the essential requirements of the directive have been met.
- Harmonized European Standards remain voluntary recommendations.

The spirit of the *Vademecum* as well as some of its provisions are not coherent with these principles which ought to remain untouched if the European standardization system shall continue to attract the participation of the best experts and shall remain successful in the future.

**Standards are voluntarily applicable technical documents developed by technical experts – not legal documents developed by legal experts. The assessment if a standard complies with its mandate and the respective legislation needs to be carried out in a practical way during the standards development process.**

- Standards shall remain voluntary and not a “*compulsory means to comply with*”. (Part I, 2.1.b))
- Technical experts shall not be required to “*have sufficient knowledge on legal requirements which are to be supported [and] on legal meaning of harmonized standards within the context of the relevant Union harmonisation legislation*”. (Part III, 2.7.2; and several clauses of Part III, Annex II 2.)
- ESOs shall not need to have “*legal capabilities to assess compliance of European standards with European legislation and Commission standardization requests.*”(Guidance Note on European Standardization)
- The ESOs should not be “*fully responsible for executing the mandates and for verification of the conformity of the published European standards or European standardisation deliverables with the corresponding Union legislation and policies.*” (Part III, Annex II 1.) It is rather the Commission together with the ESOs who are responsible, as stated in Article 10.5 of the Regulation.
- As standards are technical documents it is neither feasible nor possible to indicate a precise link between individual normative clauses of a mandated standard and supported legal requirements. This is particularly not feasible for international standards developed under the Vienna Agreement. (Part III, 2.7.4.; Part III Annex I, 1. and 2.3.)
- The *Vademecum* remains unclear on the future role of the so called New Approach Consultants. The consultants have been instrumental in the past in making sure that the technical content of a standard is helping users to adhere to the essential requirements of the respective directive. DIN recommends the Commission to keep up the practice of the New Approach Consultants.
- In order not to frustrate technical experts and threaten to render their standardization work futile, there must not be an ex-post assessment of standards in regard to their compliance with the requirements of legislation and the relevant mandate. Documents should be assessed during the



standardization work, and possibly guidance given. Whoever carries out this assessment needs to be entrusted by the Commission. Contracting consultants to carry out this assessment has proven helpful in the past. The Regulation 1025/2012, Article 10.5 does not foresee an “*ex-post judgement*” but rather judgment carried out cooperatively between ESOs and the Commission. (Part I, 4.4; Part III, Annex I, 1., whole Annex II)

### **Standards need to be market relevant. Standardization needs to respond to market needs.**

- The only possibility for stakeholders to comment on draft mandates and to give technical input is by consultation during the preparation phase. In this light, a consultation phase of two or three weeks is too short. (Part II, 4.2.2)
- A mandate should not prevent the ESOs and their stakeholders from developing deliverables in addition to the mandated work programme, provided they do not interfere with this work programme. If there is a market need, such work should be possible without an extension of the initial mandate or a new mandate. (Part I, 4.2 and 4.6; Part III, 2.6)

### **No double standard in treating standardization organizations.**

CEN, CENELEC, ETSI are recognized in the Regulation on European standardization as European standardization organizations. The Regulation imposes a number of provisions on the ESOs and their members in terms of transparency, facilitation of participation of stakeholders, and reporting. These provisions are imposed because European standards developed by the ESOs are used in European regulation. The *Vademecum* refers in different parts to “*other bodies*” developing standards. In some cases ISO and IEC are meant, in other cases unspecified organizations and fora and consortia are meant and sometimes it remains unclear. It needs to be pointed out that according to the Regulation only European standards developed by the ESOs can be referred to in legislation with the exception of technical specifications in the ICT sector. Deliverables of “*other bodies*” which are not covered by the Vienna and Dresden Agreements like ISO and IEC and are not in the ICT-sector cannot be used by the legislator.

\*The **New Approach** is a political principle of the European Union with respect to technical harmonization and standardization, based on making reference to harmonized European Standards. A feature of the New Approach is the specification of **essential requirements** in European directives. These requirements define the core aims relating to protection that the types of product covered by the directive (such as machinery) are to meet<sup>1</sup>. To guarantee the free movement of goods, products must satisfy the essential requirements of the respective directive to qualify for market release. The requirements of the directives are then specified in greater detail in harmonized European Standards.

Harmonized European Standards are developed or reviewed according to an EU mandate. A mandate is a standardization request made by the European Commission to the **privately organized** European standards organizations. The number and title of the harmonized European standards are notified to, and published in, the Official Journal of the European Union. Their national implementation is obligatory.

Application of a harmonized standard means that it can be presumed that the essential requirements of the directive have been met (“**presumption of conformity**”). Harmonized European Standards remain **voluntary recommendations** (e.g. for test methods and product requirements). There are other ways to achieve conformity with the directive. However, if a

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<sup>1</sup> <http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/>

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manufacturer produces without following the standard he has the burden of proof that he has complied with the essential requirements of the directive.

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