Welcome

The Future of Standards in Europe

The future of Standardisation in Europe – harmonisation & other recognition of standards

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Topics for discussion including

European Standardisation

- How did we get where we are?
- Harmonised Standards
- Common Specifications
- Vademecum on European Standardisation
- Annexes Z
- The Future, EU Medical Device Regulation
- Conclusions
- Questions

International and European standards organizations

International Organization for Standardization

- 161 national members
- including BSI, DIN, AFNOR, ANSI, JISC, SAC

International Electrotechnical Commission

- 76 national members
- including BSI, DKE, AFNOR, ANSI, JISC, SAC

European Committee for Standardization

- 33 national members (28 EU + 5 others)
- including BSI, DIN, AFNOR

European Committee for Electrotechnical Standardization

- 33 national members (28 EU + 5 others)
- including BSI, DKE, AFNOR

Europe

CEN

- Comité Européen de Normalisation
- **33** National Members
- CEN currently has **1994** Technical Bodies, mostly Technical Committees and Working Groups
- In **2012**, CEN
  - produced **1148** documents
  - bringing number of live documents to **14,885**
  - with **3337** documents in preparation

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Interaction with the European Commission

New Approach Directives

- Legislation and standards for the free movement of goods in Europe

New Approach directives

Fundamental principles

- A new type of directive: essential requirements.
- Standardization to support legislation.
- Voluntary application of standards, but…

  …products in compliance have presumption of conformity.

New Approach directives

Examples

Low voltage equipment • Simple vessels • Toys • Electromagnetic compatibility • Construction products • Machinery • Lifts • Personal protective equipment • Non-automatic weighting instruments • Medical devices • Active implantable medical devices • Gas appliances • New hot water boilers fired with liquid or gaseous fluids (efficiency requirements) • Explosives for civil uses • Equipment and protective systems in potentially explosive atmospheres • Recreational craft

www.newapproach.org

New Approach directives

Essential requirements

- Lay down the necessary elements for protecting the public interest.
- Are mandatory. Only products conforming to essential requirements may be placed on the market and put into service.
- Must be applied as a function of the hazards inherent to a given product.

European Harmonised Standards

- European Union's "New Approach" to standardization (1985).
- EU Directives define the 'essential requirements' for safety and other aspects of public interest which should be satisfied by products and services being sold in the EU.
- On receiving a formal request (mandate) from the Commission, CEN and CENELEC must prepare technical standards that facilitate compliance with these 'essential requirements'.
- At the same time, public authorities are required to recognize that all products manufactured and services provided in accordance with harmonized standards are presumed to conform to the 'essential requirements'.
    - When businesses make use of harmonized standards, there is a 'presumption of conformity' that their products and services comply with EU legislation.

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Where are we now?

Challenges with European Standards

CEN/CENELEC Management Centre (CCMC) published some data from an analysis completed in January 2016:

- European Standards (including amendments/corrigenda) referenced in the OJEU under any Medical Devices Directives(s) – 344
- European Standards (including amendments/corrigenda) explicitly rejected by the European Commission for OJEU citation under any Medical Devices Directive(s) – 72
- European Standards (including amendments/corrigenda) intended to be cited, offered to the European Commission but not yet cited, under any Medical Devices Directive(s) – 233 i.e. 57% of the medical European Standards offered for OJEU citation.
- Not a helpful situation for medical device manufacturers who wish to use Standards as part of their Conformity Assessment procedures, in particular as a Harmonised Standard provides for "Presumption of Conformity".

Regulation (EU) 1025/2012 - ..on European Standardisation

The opening text, the primary objective of standardisation is the definition of voluntary technical or quality specification with which current and future products, production processes or services can apply. …. Later text speaks to the important role standards have to play in the "Internal Market".

Article 10.5 -

The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the documents referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.

- **Harmonisation Process executed by European Commission (e.g. Annexes Z for 13485:2016)**

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Regulation (EU) 1025/2012 - ..on European Standardisation

Article 10 cont'd

Article 10.6

Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of such harmonised standard without delay in the Official Journal of the European Union or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.

So for ISO 13485:2016 we are anticipating citation in the OJEU in the May/June timeframe.

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Vademecum on European Standardisation

Vademecum – what does it mean?

Definition from the Concise Oxford English Dictionary

a handbook or guide kept constantly at hand

Vademecum on European Standardisation

Set of documents produced by the European Commission DG GROW

Guidance on the interface between European legislation and policies and standardization

Comprise three documents covering:

- The role of standardization requests
- The preparation of standardization requests
- The delivery of standards covered by standardization requests.

Specific issues include

- role of the different players (EC, ESOs, industry)
- scope and validity of requests
- assessment of compliance of standards with the request
- planning of requests and consultations
- work programmes
- Annex Z
- changes to harmonized standards.

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DECISION (CEN) BT C34/2015

Subject: Medical Harmonized Standards – Proposal for an Annex ZA format for a practise of dating normative references.

BT noting,

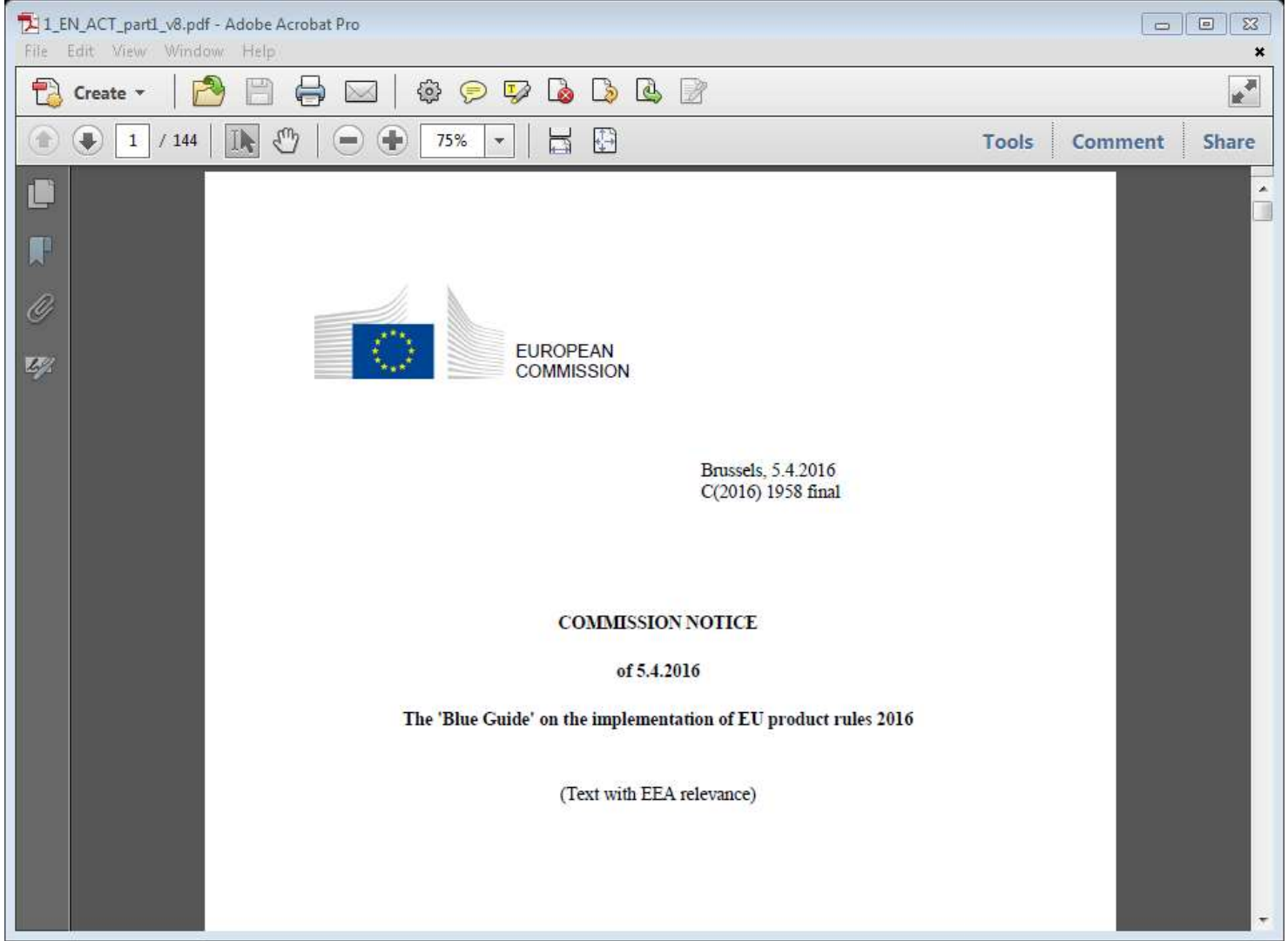
- that for several years, the European Commission systematically rejects for OJEU citation a large proportion of Harmonized Standards in support of the Medical Devices Directive (93/42/EEC), the Active Implantable Medical Devices Directive (90/385/EEC) and the *In Vitro* Diagnostic Medical Devices Directive (98/79/EC);
- that the main reasons for such rejections are related to the content of the Annexes ZA and to the use of undated normative references;
- that in December 2014, DG SANCO offered to the medical New Approach Consultants a one-day training on its expectations in terms of Annexes ZA and normative references;
- that, as the outcome of the training, the use of the Annex ZA templates presented in Annexes 1, 2 and 3 of BT N 9879, as well as the practice of dating all normative references as described in Annex 4 to BT N 9879 would substantially increase the likelihood of OJEU citation;
- that these practices were discussed at the BT/TCMG meeting of 2015-03-04 and TCMG was in favour of submitting such a proposal to CEN/BT for formal approval;

DECISION BT 41/2015

Subject: Harmonisation of Annexes ZA required for publishing references of Harmonised Standards in the OJEU – Implications for Medical Devices

BT noting,

- The proposal of the Commission regarding implications for the Annex ZA/ZZ of harmonised Standards resulting from the implementation of the New Legislative Framework (NLF) in the revised/recast New Approach Directives (see the EC letter dated 2105-05-29 in BT N 10072).
- That acceptance of such provisions would have implication for the drafting of Annexes ZA in the field of Medical Devices.
- Decision BT C34/2015 – (see previous slide).
- DG GROW.D.4 "Health Technology & Cosmetics" stated that the new Annex ZA template, if adopted by BT, would be acceptable to them, provided the four notes adopted through C34/2015 are kept.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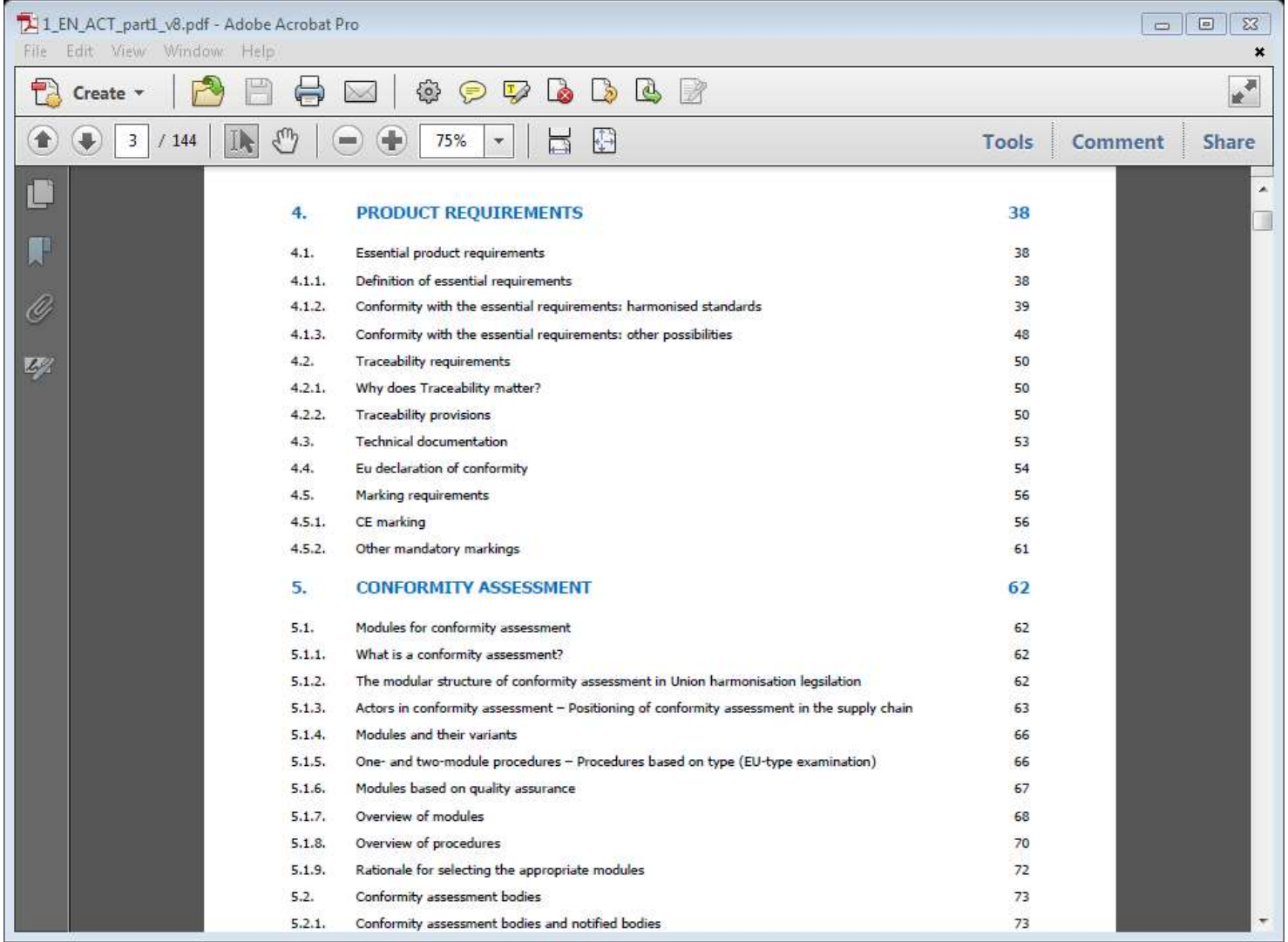
of 5.4.2016
The 'Blue Guide' on the implementation of EU product rules 2016
(Text with EEA relevance)

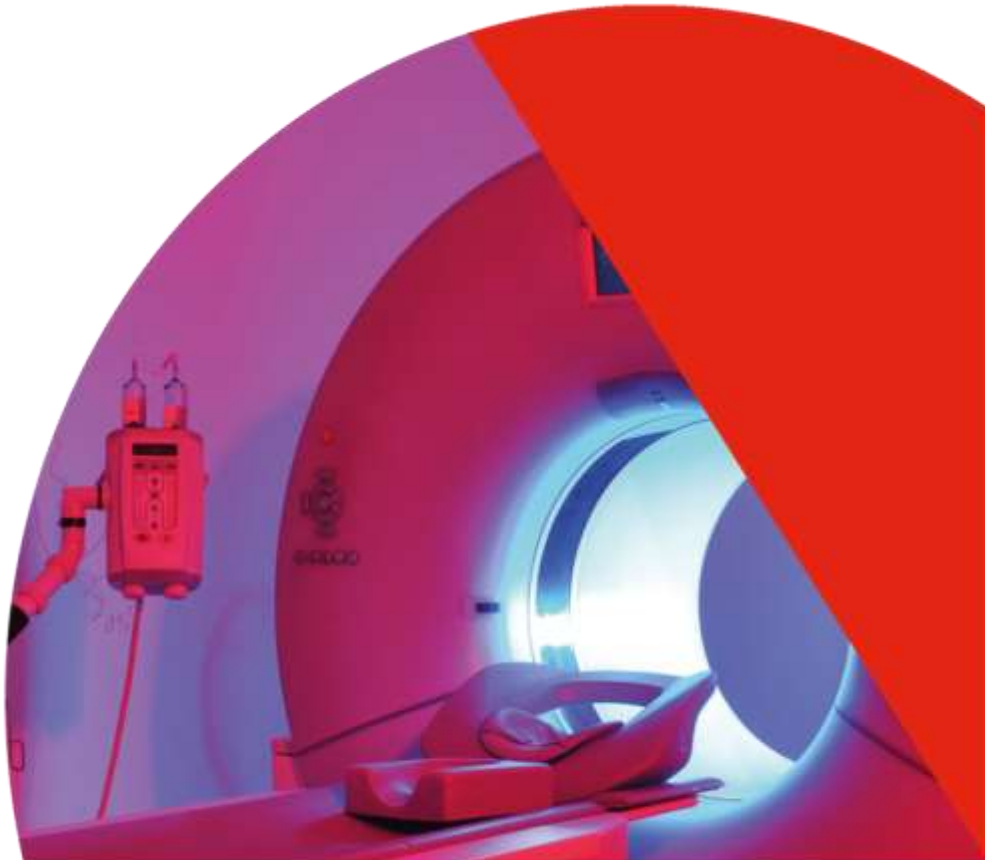


The “Blue Guide” on the implementation of EU Product Rules 2016

- Clause 4.1.2 – Conformity with the Essential Requirements: Harmonised Standards
  - 4.1.2.1 – Definition of a Harmonised Standard
  - 4.1.2.2 – Role of Harmonised Standard
  - 4.1.2.3 – Process to harmonised standards providing a presumption of conformity
  - 4.1.2.4 – The Presumption of conformity
  - 4.1.2.5 – Withdrawal, restriction or prevention of the presumption of conformity
  - 4.1.2.6 – Revision og harmonised standards
- Clause 4.1.3 – Conformity with the Essential Requirements: Other Possibilities

For the Future

Harmonised Standards & Common Specifications



Proposed EU MDR text

Article 6 – Harmonized Standards

Devices which are in conformity with the relevant harmonized standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.

….. also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance system, clinical investigations, clinical evaluation or post-market clinical follow-up.

Reference to harmonized standards also includes the monographs of the European Pharmacopoeia ….., notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided references to those monographs have been published in the Official Journal of the European Union.

Proposed EU MDR Text

Article 7 – Common Specifications

Where no harmonized standards exist or where relevant harmonized standards are not sufficient, the Commission, ….. may adopt common specifications (CS) in respect of

- general safety and performance requirements …,
- technical documentation …,
- clinical evaluation and post-market clinical follow-up …
- requirements regarding clinical investigation

the CS shall be adopted by means of implementing acts.

Devices which are in conformity with the CS … shall be presumed to be in conformity with the requirements of this Regulation covered by those CS.

Manufacturers shall comply with the CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent

… manufacturers of products *[without an intended medical purpose]* listed in Annex XV shall comply with the relevant common specifications for those products.

EU Proposed Medical Device Regulation

Text in final stages of review – 2 key topics

- Delegated Acts, covering different articles:
  - Amend or supplement the conformity assessment procedures set out in Annexes VIII to XI
  - Amend of supplement the minimum content of certificates set out in Annex XII, in the light of technical progress
  - etc

- Implementing Acts, covering different articles:
  - Specify the modalities and procedural aspects with a view to ensuring harmonised application of UDI
  - List of codes and corresponding types of devices to describe the scope of designation of Notified Bodies which the Member State shall indicate in their notification
  - etc

Annexes Z

Moving towards the EU MDR adoption - remember

- Moving to the Transition, standards will be Annexes Z for both the relevant Directives and Regulations.
- Standards including the Annexes Z where applicable will need revision to reflect the changes in Annex 1 – General safety and performance requirements.
- As new Annexes Z are prepared these in turn could identify additional gaps which will need to be addressed.

Some conclusions

- I hope I have provided some explanations, but may be not the answers.
- The position of European Standards has not changed in the new regulation, under the New Approach, Standards have a critical role to play.
- The introduction of Common Specifications, how they will be developed and implemented has yet to be seen.
- CEN have recently initiated a Project to investigate and determine the cause of the delay to standards achieving harmonisation status.

European Standards
Standardisation Policy
Harmonised Standards
Notification System
Standardisation requests
Key Players
Standardisation and SMEs
Vademecum on European standardisation
Single Market and

Vademecum on European standardisation

This Vademecum compiles key documents from the European Commission on European standardisation policy and related practice. It provides guidance without having legal status.

The main aim of the Vademecum is to serve as a guide for:

- **Commission officials** - it will enable them to use European standardisation as a tool for the implementation of European policies and legislation
- **EU countries** - it will help them to understand the Commission's European standardisation policy and the mechanisms of referring to European standards in European policies and legislation
- **Stakeholders** - to gain a clear picture of the policies and processes of the Commission in this field.

The publication of the Vademecum contributes to the transparency and accessibility of Commission policy on European standardisation.

1. **Standardisation requests (role, adoption and execution)**
   SWD(2015) 205 final of 27/10/2015 Vademecum on European

Single Market and Standards - links

- News
- Events
- Tools and Databases
- Contracts and grants
- Public consultations
- Publications

1. **Standardisation requests (role, adoption and execution)**

   SWD(2015) 205 final of 27/10/2015, Vademecum on European standardisation in support of Union legislation and policies

   - Part 1 - Role of the Commission's Standardisation requests to the European standardisation organisations (available in all EU languages, 249 kB)
   - Part 2 - Preparation and adoption of the Commission's standardisation requests to the European standardisation organisations (available in DE/EN/FR, 303 kB)
   - Part 3 - Guidelines for the execution of standardisation requests (available in all EU languages, 155 kB)

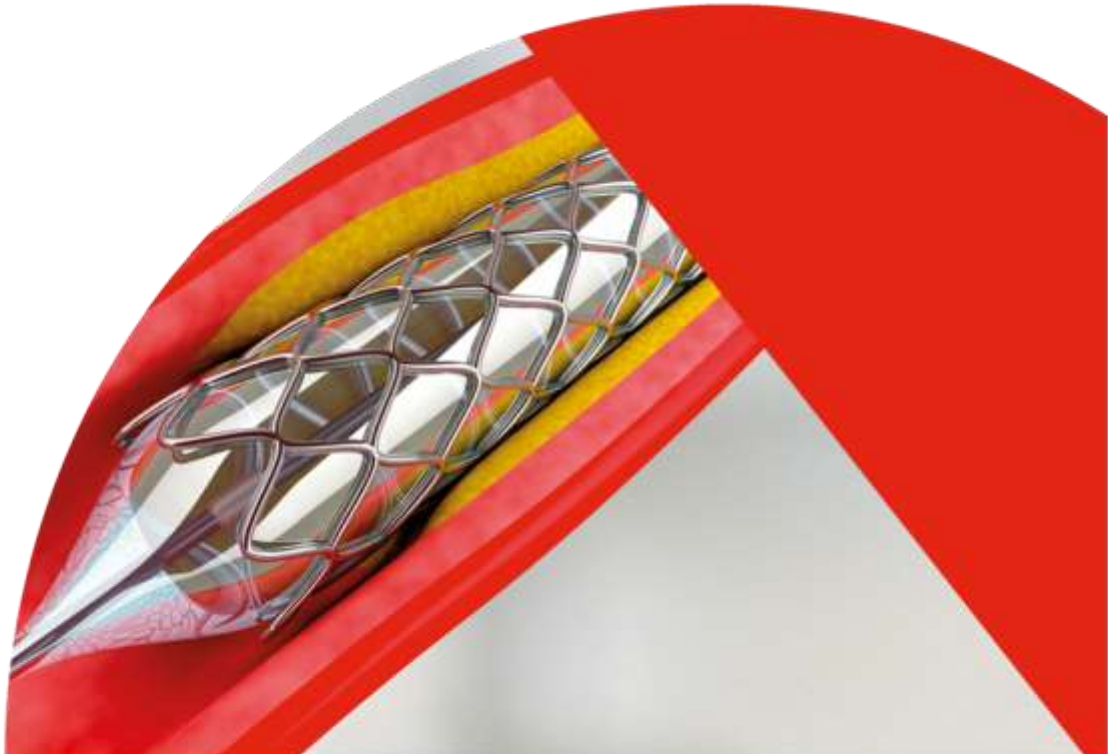
   Follow-up of mandates (411 kB) [Note: certain terminology and references contained in this document published in 2009 are outdated]

2. **Role and use of harmonised standards in harmonisation legislation for products**
   - 'Blue Guide' on the implementation of EU product rules (see points 4.12 and 10.6)
3. **Regulatory use of standards**
   - Methods of referencing standards in European legislation (232 kB)

Related resources

- Regulation (EU) No 1025/2012
- General Guidelines for the Cooperation between CEN, CENELEC and ETSI and the European Commission and EFTA
- Directives and Regulations under the New Legislative Framework (NLF)
- References to harmonised standards and other European standards published in the OJEU
- Better Regulation 'Toolbox': The choice of policy instruments. See chapter 3.2: Technical standards

Questions?



Thank you for your time & attention

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