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EUROPEAN COMMISSION ACTS TO MAKE STANDARDIZATION IN THE SINGLE MARKET MORE EFFICIENT

On 22 November 2018, the European Commission presented an action plan to enhance efficiency, transparency and legal certainty in the development of harmonized standards for a fully functioning Single Market.

Largely voluntary and industry-driven standards reduce costs, promote innovation, ensure interoperability between different devices and services, and help companies to access markets. The EU has harmonized standards in a range of areas, such as chemicals, construction products, cosmetics, toy safety, medical devices and packaging. With the actions presented, the Commission responds to the demands of stakeholders and acts to ensure that the European standardization system meets the challenged of rapidly evolving technological developments, emerging economic trends and growth models while promoting synergies with international and global standards.

The Communication on harmonized standards provides an overview of the functioning of the European standardization system, takes stock of the initiatives launched in recent years and presents four key actions that the Commission will immediately undertake to enhance the efficiency, transparency and legal certainty for the actors involved in the development of harmonized standards:

- Eliminate, as rapidly as possible, the remaining backlog of harmonized standards that are not yet published in the Official Journal of the European Union;

- Streamline internal decision making processes, in particular the decision of publishing the references of harmonized standards in the Official Journal;

- Elaborate a guidance document on practical aspects of implementing the Standardization Regulation;

- Reinforce, on an on-going basis, the system of consultants to support swift and robust assessments of harmonized standards and timely publication in the Official Journal.

The Communication on harmonized standards is available via this link.

We selected this topic, given the importance of harmonized standards for medical devices (see link). A large number of harmonized standards are available for medical devices and such harmonized standards allow manufacturers to demonstrate that their devices comply with EU legislation.

For the dental sector the following harmonized standards are relevant:

- EN 1639:2009 — Dentistry — Medical devices for dentistry — Instruments
- EN 1640:2009 — Dentistry — Medical devices for dentistry — Equipment
- EN 1641:2009 — Dentistry — Medical devices for dentistry — Materials
- EN 1642:2011 — Dentistry — Medical devices for dentistry — Dental implants

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

Sarah – Evi

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