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NEW ONLINE PORTAL WILL EASE TRANSITION FROM MEDICAL DEVICE DIRECTIVES TO MEDICAL DEVICES REGULATIONS

The recently launched Medical Devices section on the European Commission's website has been revamped to help smooth the transition to the new Medical Devices Regulation (the '**MDR**') and the *In Vitro* Diagnostic Medical Devices Regulation (the '**IVDR**'). The MDR and the IVDR bring EU legislation into line with technical advances, changes in medical science, and progress in law making. The Regulations entered into force on 25 May 2017 and will progressively replace the existing Directives. They will be fully applicable in May 2020 (for medical devices) and May 2022 (for *in vitro* diagnostic medical devices).

The revamped website presents the new regulatory requirements in various sections targeted at impacted actors (manufacturers, importers, health institutions, authorities in non-EU countries and others). It explains the main differences between the current Directives and the new Regulations and highlights the timeline for the transition along with deadlines for implementation.

The new portal also offers resources targeted at journalists in the medical industry, including:

- Factsheets explaining the impact of the Regulations on stakeholders across the sector (see also the **European Highlight of 16 January 2019**, which highlighted the factsheet intended for authorized representatives, importers and distributors of medical devices and *in vitro* diagnostic medical devices).

- Frequently Asked Questions that shine light on technical aspects of the Regulations.

- A contacts page through which journalists can request additional information.

The website is available via this link and even contains a dedicated page intended for authorized representatives, importers and distributors.

We informed you about this development because medical device legislation is highly relevant for dental distributors in Europe.

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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