2026

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Free webinar

19 February 2026
12.00 PM CET

Theme:

EU In Vitro Diagnostic Regulation (IVDR) Implementation.
State of Play and Challenges

Todor Darakchiev

Bulgarian Drug Agency

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The webinar will be given by **Todor Darakchiev**, M. Pharm., Head of Division Medical Devices Department, Market Supervision and Inspections,, Bulgarian Drug Agency (BDA), who will examine the background, scope and implementation of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Regulation (EU) 2017/746 lays down the rules concerning the placing on the market, making available on the market, or putting into service of in vitro diagnostic medical devices for human use and accessories for such devices in the European Union. This Regulation also applies to performance studies concerning such in vitro diagnostic medical devices and accessories conducted in the European Union.

Todor Darakchiev is Head of Division “Medical Devices” in the department Market Supervision and Inspections at the BDA. He has been working in the field of medical devices regulation since he started to work for the BDA in 2000. During his career in the BDA he gained regulatory experience as a chief expert for issuing of marketing authorisations of medical devices (till 2006), and as a chief inspector for medical devices and medicinal products (since 2007). Todor Darakchiev participates in the meetings of the EU Competent Authorities for Medical Devices as BDA representative. During the period 2007 – 2017 he attended several workshops for medical devices organised by TAIEX (1). In the beginning of the Bulgarian EU membership, he was a member of a working group responsible for transposition of the European legislation for medical devices. From 2011 to 2012 Todor Darakchiev participated in an interdepartmental project ‘’Creation of digital database of medical devices paid with public resources” as a coordinator. After adoption of the EU Regulations for Medical Devices and In vitro Diagnostic Devices he was designated as a member of the Medical Device Coordination Group (MDCG) in the EU. Todor Darakchiev has also become a member of a working group for amendment of the Bulgarian Law on Medical Devices in connection with the implementation of the new legislation in the sector.

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(1)TAIEX: Technical Assistance and Information Exchange, a key European Union instrument for institutional capacity-building worldwide, providing targeted and rapid support to public administrations in EU candidate countries and beyond