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Regulatory review

Your monthly medical device update
August 2021

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[Phthalates and endocrine disruptors | New whitepaper](#)

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We are delighted to announce that all our digital pre-applications for CE marking, UKCA and QMS services are now online and form part of our pre-application portal. The portal will allow you to access

the pre-application process through a digital interface. We are excited to share our new journey into digital applications and the replacement of our Company Information Forms.

In addition, we have ensured that the system intelligently routes pre-application activities and issues alerts and notifications to you with inbuilt validation of the data you input. This will allow you to have greater interaction with the portal with all your applications in one, easy to access place, whilst tracking your application in real-time.

Please chat to your BSI Commercial contact to arrange access to the system. Or if you are new to BSI please complete the online form:

[Complete the form](#)

This webinar was presented by
Maddalena Pinsi, Regulatory Lead, BSI.

The webinar offered notified body
insights for all people involved in
working towards an IVDR and MDR
application.

If you missed the webinar or were not able to join you can [view the recording and presentation slides here](#).

Join BSI's Theresa Jeary, Technical Specialist and Scheme Manager, as

Many phthalates have the potential to cause hormonal disruption, however, it was only recently (January 2020) that experts produced a useful consensus paper (La Merrill et al., 2020) which defined the key characteristics of endocrine-disrupting (ED) chemicals as a basis for the identification of their intrinsic hazard. This whitepaper summarizes the evaluation of phthalates and ED substances in medical devices.

[Download whitepaper](#)

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