


BSI 2019 EU In Vitro Diagnostic Regulation Roadshow

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| Datum: | 22.10.2019 | Die Ar |
| Ort: | Berlin | Ve |
| Kosten: | 175 € | Kc |
| Adresse: | Radisson Blu Hotel Berlin Karl-Liebknecht-Str. 3 10178 Berlin | Sp |
| Anfahrt: |  Anfahrtsskizze | Dc |
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folgenden Informationen sind lediglich auf Englisch verfügbar:

The IVD industry is undergoing significant change – Are you prepared?

BSI is proud to announce the upcoming EU In Vitro Diagnostic Regulation (IVDR) Meeting in Berlin, a full day event for the IVD device manufacturer regulatory affairs, quality assurance and related consulting community. Join our experts and guest speakers to learn about some of the most significant changes to the European Regulatory and Compliance Expectations for CE marking.

Topics will include:

- IVDR Overview, Classification, Grouping Devices
- Technical Documentation Requirements
- New Requirements for Performance Evaluation
- Post-launch Requirements
- Market Access and Reimbursement
- Workshop: Using the Remaining Transition Period Effectively
- Interacting with the Notified Body