**MEDICAL SPICE**

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**Background:**

A significantly increased proportion of software applications are classified as medical devices and must be developed in a regulatory compliant manner.

The number of software suppliers *requiring compliance with the medical device regulations* is growing.

**Aim:**

To develop and commercialize an end-to-end solution for medical device software regulatory compliance that integrates the regulatory requirements of the medical device industry with generic software engineering best practices.

***Deliverables:***

* Medical SPICE process models;
* a measurement framework for regulatory compliance/ process assessment;
* interfaces between Medical SPICE and a medical device QMS ;
* training to companies on medical device software processes;
* a suite of assessment methods;
* a Conformity Assessment scheme;
* an Assessor Training and Certification scheme;
* International roll-out of Medical SPICE.

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