General Safety and Performance Requirements (GSPR)

The core of the MDR are the General Safety & Performance Requirements. The medical device must comply to all these requirements and the manufacture must have evidence that the device conforms to these requirements. There are in total 17 pages in Annex I of the MDR divided in

- 9 general requirements (risk control)
- 13 requirements regarding design & manufacture
- 1 requirement regarding information supplied with the device (labelling)

There are a number of software specific requirements, in summary:

- Software shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.
- Software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation
- Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts
- Software intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).
- Manufacturers shall set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended