ISO 13485 vs MDR

ISO 13485 Medical Devices is an internationally recognized Quality Management System (QMS) standard for producing medical devices. It was harmonized to MDD in 2017 and it remains the standard used to prove conformance to the MDR.
When looking at the individual requirements of MDR, it is clear various clauses are not covered under ISO 13485. These include various aspects relating to general safety and performance requirements in relation to risk. For example:

- Annex I, Chapter 1, 2 – reduce risk as far as possible
- Annex I Chapter I, 3, a – establish a risk plan for each device
- Annex I Chapter I, 4 – managing risk so that residual risk is acceptable
- Annex 1, Chapter I, 8 – risk benefit analysis to ensure all risks are acceptable when weighed against benefits
- Annex I Chapter I, 4 – manufacturers must reduce risk, provide measures alarms etc., and inform patients of any residual risk

Other MDR provisions that are not covered by ISO 13485 include:

- MDR Article 10 4 MDR – Commission is empowered to adopt delegated acts in accordance with Article 115
- MDR Article 10 Ref 16 – manufacturers must have sufficient financial coverage in respect to potential liability from defective devices
- MDR Article 10 6 MDR – draw up a Declaration of Conformity (DoC) after successful conformity assessment. This does not apply to custom made or investigational devices
- Annex XI A5 A – manufacturer must have authorized representative if company is based outside the EU and they must ensure they meet the requirements for the issuance of a (DoC)

There are also various sections where adherence to ISO 13485 only provides partial coverage of the requirements in MDR. For example, it only partially covers clauses 7.1, 7.3, 7.5 in Annex I, Chapter 1, 1. These relate to the requirement that a device should be suitable for its intended use and must be safe and effective and should not compromise the clinical condition or the safety of the patient, operators, and any other user. Any risks associated with its use must be outweighed by its benefits and should be compatible with a high level of protection and health and safety.
Among the other MDR requirements that are not covered by ISO 13485 are provisions relating to unique device identification (UDI), technical documentation, continual improvement, post market surveillance, labeling, recalls, ergonomics and device lifetimes.

ISO 13485:2016 remains the current state of the art standard by which manufacturers may show compliance to the quality system requirements of the MDR. It demonstrates that a company's QMS is designed to deliver consistent, high quality products onto EU markets.

It should be remembered that ISO 13485 is recognized internationally, making those that adopt the standard more attractive in other markets. For example, under the Medical Device Single Audit Program, certification is a requirement before a product can be placed on the market in Canada, and it will eliminate or reduce US FDA onsite inspections of facilities. Finally, certification will aid the registration process for devices in any jurisdiction covered by MDSAP.