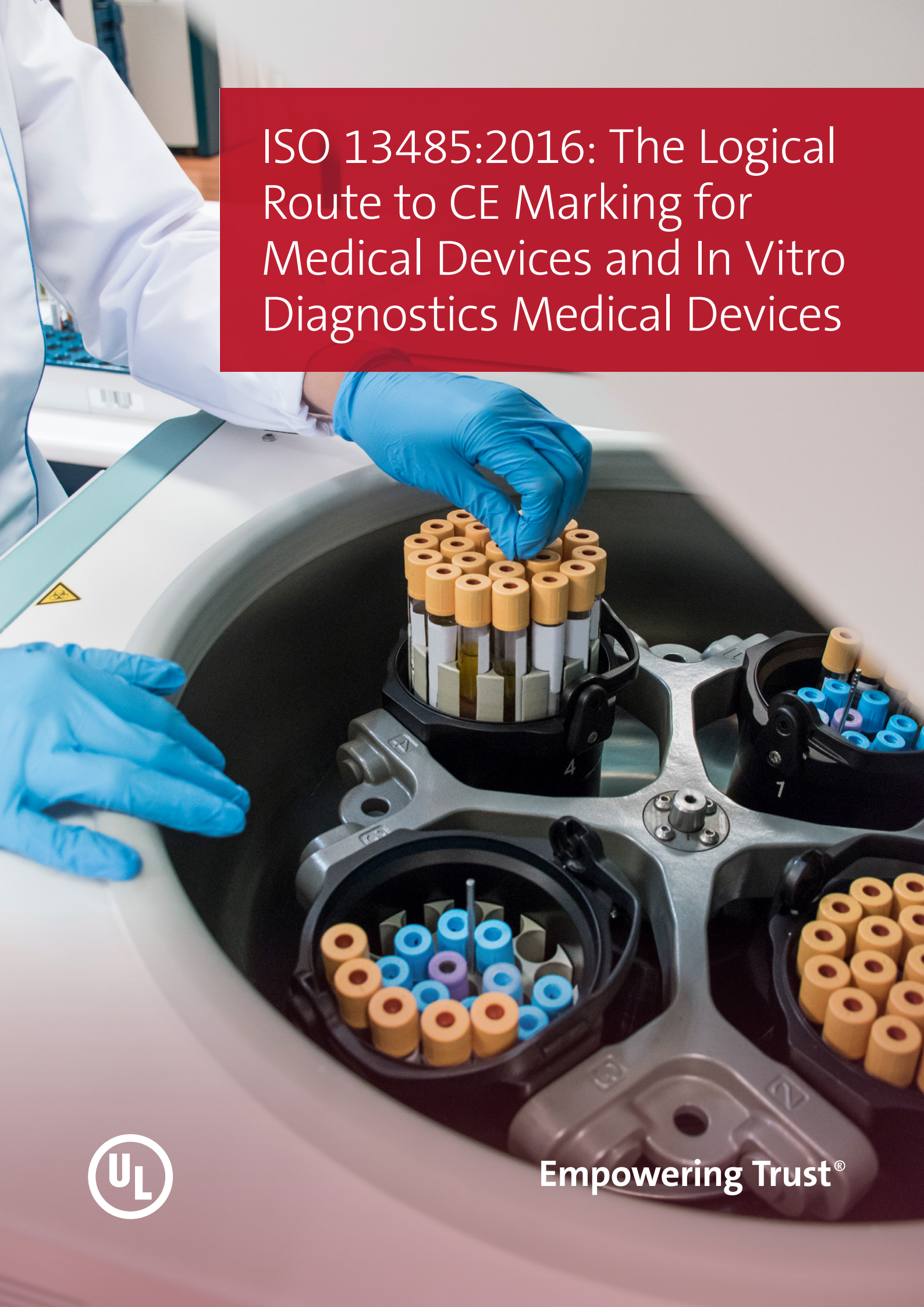
ISO 13485:2016: The Logical Route to CE Marking for Medical Devices and In Vitro Diagnostics Medical Devices



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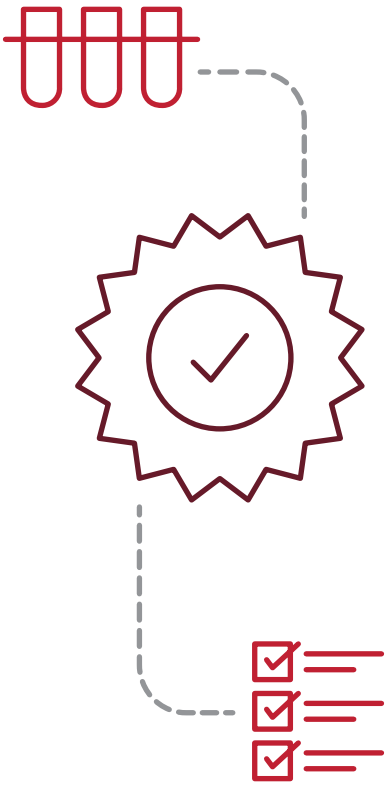
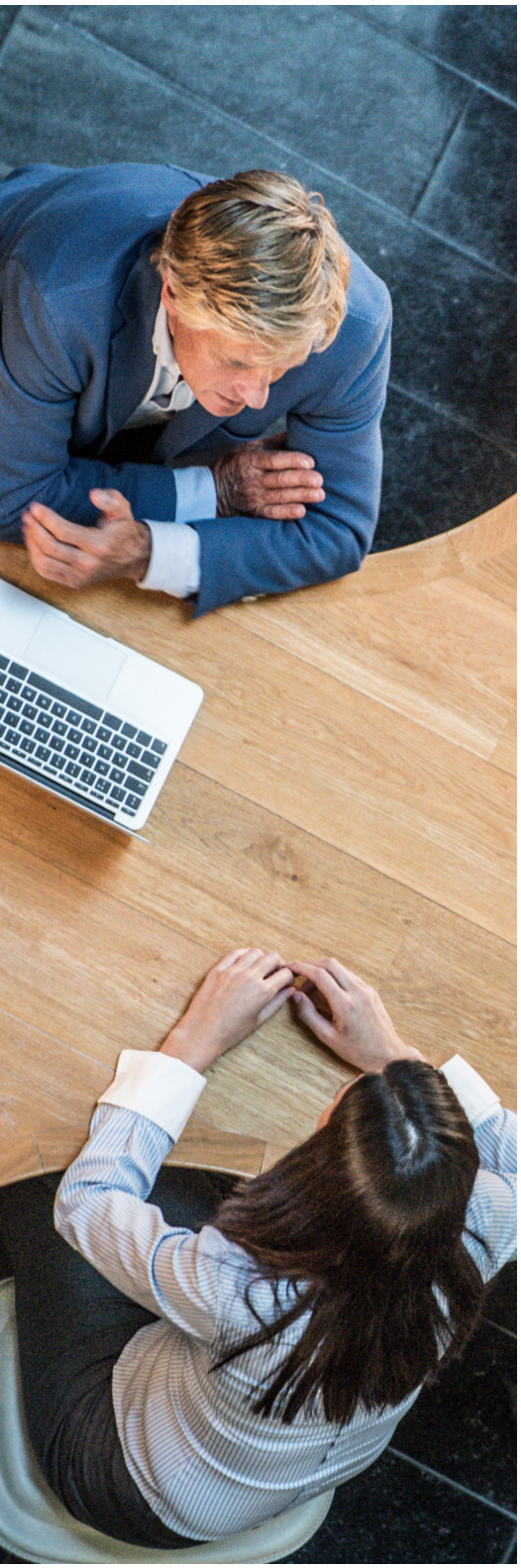
What Is ISO 13485:2016?

ISO 13485:2016 is the standard for Medical Devices — Quality management systems — Requirements for regulatory purposes.

This standard is useful because it specifies requirements for a quality management system (QMS) where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

ISO 13485 is an essential standard in the medical device industry and the most used international standard for QMSs.





Why do you need it?

If you are a manufacturer of medical devices not certified for ISO 13485:2016 and currently selling medical devices into the European Union (EU), a few upcoming regulation changes might make you reconsider your position: Regulation 2017/745 (Medical Device Regulation-MDR) with a May 26, 2021, date of application and Regulation 2017/746 (In Vitro Diagnostic Regulation-IVDR) with a May 26, 2022, date of application.

These two regulations are more prescriptive than the current relevant directives where a QMS is still required, whereby requirements on QMSs are more detailed (see table page 4 for correspondence with ISO 13485:2016 and IVDR).

For in vitro diagnostic medical devices, at least, it is expected that 80% of the current devices on the market will need a Notified Body review for CE marking in which an audit of the QMS will be conducted. (See "How can UL help you achieve CE certification?" for guidance about how UL can help with review and processes).

Right now, approximately 80% of in vitro diagnostic medical devices are not subject to this Notified Body oversight and are therefore self-declared. A proportion of these manufacturers do not have ISO 13485:2016 certification, and the transition to CE marking without an established QMS reviewed against ISO 13485:2016 might prove to be a real hurdle.

How could ISO 13485 help you get CE marking?

The current ISO 13485:2016 is not mandatory; however, the current medical device directives and regulations (MDD, IVDD, MDR and IVDR[1]) require that manufacturers have a QMS in place.

Furthermore, EN ISO 13485:2016[2] is listed in the Official Journal of the European Union as the harmonized standard for medical devices in support of In Vitro Diagnostic Medical Device Directive 98/79/EC and in support of the Medical Device Directive 93/42/EEC[3]. This is the only QMS standard mentioned in the Official Journal of the European Union in support of the Medical Device Directives.

Therefore, it seems logical to opt for ISO 13485:2016 for your QMS in order to facilitate compliance with CE requirements.

See below the correspondence/correlation between the IVDR requirements for QMS (chosen as an example) and ISO 13485:2016. The requirements for the MDR are similar and can also be found in article 10 of the regulation.

EU IVDR QMS requirements	Corresponding clauses in the standard
A strategy for regulatory compliance	4.1, 7.2.1, 7.2.2
Management of modifications to the devices	4.1.1, 7.3.9
General safety and performance	7.3.3
Responsibility of the management system	5
Resource management	4.1.3, 5.1, 5.6.3, 6, 7.1, 7.3.2
Selection and control of suppliers and subcontractors	4.1.5, 7.4
Risk management	4.1.2. 7.1
Performance evaluation	7.3 (7.3.7)
Product realization, including planning, design, development, production and service provision	7.3, 7.5
Verification of the Unique Device Identifier (UDI) assignments	7.5.8, 7.5.9
Post-market surveillance system	8.2.1, 8.2.2, 8.5.1
Communication with competent authorities, Notified Bodies, other economic operators, customers and/or other stakeholders	5.5.3,7.2.3, 8.2.3
Reporting of serious incidents and field safety corrective actions in the context of vigilance	8.2.2, 8.2.3
Corrective and preventive actions and verification of their effectiveness	8.5.2, 8.5.3
Monitoring and measurement of output, data analysis and product improvement.	8.2, 8.4, 8.5

Note: Correspondence of EN ISO 13485:2016 clauses with the In Vitro Diagnostic Medical Device Directive 98/79/EC and the Medical Device Directive 93/42/EEC can be found in Annexes ZC and ZB, respectively.

The QMS shall address at least the above aspects (see article 10 of the IVDR).

Most of the requirements of the MDR, IVDR, IVDD and MDD, with regards to the QMS, are covered in ISO 13485:2016, making this standard the most suitable tool for supporting compliance with QMS requirements of current directives and regulations.

What happens during a CE audit and how is ISO 13485:2016 used?

For CE certification, most manufacturers currently choose the full quality assurance system conformity assessment route under the directives. In this route, a QMS audit is performed as well as an examination of the design of the product for specific products.

Similarly, manufacturers are likely to use the conformity assessment route based on QMS audit and technical documentation for the new regulations.

Both of these options require an assessment of the QMS during an audit and evaluation of the technical documentation for the devices to be listed on the manufacturer certificate.

During the QMS audit, the auditor will assess the manufacturer's QMS against the medical device or in vitro diagnostic medical device directives and/or regulations. For this, EN ISO 13485:2016 will be used as a reference document. Currently, most ISO 13485:2016 and CE audits are conducted jointly. Having only one audit covering these requirements saves time and costs for the manufacturer, rather than two similar audits within the year.

How can UL help you achieve CE certification?

UL's global presence can help bring your products to market quickly, and our ISO 13485 program is accredited by the United Kingdom Accreditation Service (UKAS).

Our team includes full-time auditors around the world, many of whom can speak the manufacturer's local language. UL provides integrated audits of your management system to take advantage of the similar requirements synergy among your various QMS needs[4], including ISO 13485 and CE marking.

UL offers CE Conformity Assessment through our unique partnership with the Polish Centre for Testing and Certification (PCBC) Notified Body.

With the date of application of Regulations 2017/745 and 2017/746 fast approaching, the need to choose a registrar that can also provide CE marking has never been greater.

UL has everything you will need for ISO 13485:13485 certification and CE marking.

Please note that UL has recently entered discussion with the Medicines and Healthcare products Regulatory Agency (MHRA) to provide the UKCA mark to manufacturers wishing to sell devices in Great Britain.

Endnotes

1. MDD stands for Medical Device Directive 98/79/EC
   IVDD stands for In Vitro Diagnostics Medical Device Directive 93/42/EEC
   MDR stands for Medical Device Regulation 2017/745
   IVDR stands for In Vitro Diagnostics Medical Device Regulation 2017/746

2. EN ISO 13485 is a parallel standard issued in the EU. The requirements in both are identical. The European version of the standard (EN ISO 13485) also includes annexes that align ISO 13485:2016 requirements to the three EU directives for medical devices: Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC.

3. It is expected that an updated list will be published in support of the IVDR and the MDR.

4. Note that UL also offers ISO 9001, ISO 14971, Medical Device Single Audit Program (MDSAP), National Institute of Metrology, Standardization and Industrial Quality (INMETRO), Indian Certification for Medical Devices (ICMED) and other audit options.

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