Regulation stage

Regulatory requirements in Northern Ireland guide

Regulatory requirements in Northern Ireland

Northern Ireland and Great Britain (England, Scotland and Wales) have different medical device regulatory requirements.

In Northern Ireland, medical devices and in vitro diagnostic medical devices being placed on the market are subject to the EU Medical Device Regulation (EU MDR) and In Vitro Diagnostic Regulation (EU IVDR). Devices placed on the Northern Ireland market generally require a CE mark.

In Great Britain, medical devices and in vitro diagnostic medical devices being placed on the market are subject to the UK Medical Devices Regulations 2002 (UK MDR 2002). Devices placed on the Great Britain market generally require a UKCA mark, although CE-marked devices may also be placed on the Great Britain market in line with current UK government arrangements.

Innovators intending to market their products in Northern Ireland or Great Britain should ensure they understand the applicable regulatory requirements, including conformity assessment and marking requirements, and seek advice from the MHRA where appropriate.

For further information, visit the MHRA guidance on the regulation of medical devices in Northern Ireland.