United Kingdom
World Bank income group: High income

Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Responsibilities of the NRA: The role of the MHRA is to protect and promote public health and patient safety. One way it does this is by regulating medical devices in the UK – ensuring they comply with the Medical Devices Regulations. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf

Medical device definition
Medical device defined: Yes
Text: Medical device means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which—
(a) is intended by the manufacturer to be used for human beings for the purpose of—
(i) diagnosis, prevention, monitoring, treatment or alleviation of disease,
(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
(iii) investigation, replacement or modification of the anatomy or of a physiological process, or
(iv) control of conception; and
(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device[..] The Medical Device Regulations No. 618, 2.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately.

Medical device classification
Classification: Yes
Categories: Medical devices are classified into class I, IIa, IIb, or III. The Medical Device Regulations, 7.
Classification rules details: N/A

Essential principles
Essential principles: Yes
Details: One may not place a medical device on the market or into service unless that device meets essential requirements. The Medical Device Regulations, 8.

Conformity assessment
Conformity assessment bodies: Yes
Details: Yes A notified body’s tasks will vary depending on the classification of the products concerned and the conformity assessment route a manufacturer has chosen. The conformity assessment procedures can be found in the annexes of each of the 3 pieces of legislation. The Medical Device Regulations, 9. https://www.gov.uk/government/publications/notified-bodies-for-medical-devices/notified-bodies-for-medical-devices
Pre-marketing / procedure: N/A

Reliance
Reliance: Yes
Details: The UK, as a member of the EU, relies on harmonized conformity assessment procedures. The Medical Device Regulations.
Jurisdictions: EU, New Zealand; Australia ; USA; Canada - http://www.legislation.gov.uk/uksi/2002/618/schedule/2/made
**Clinical investigation**

**Clinical investigation controls:** Yes  
**Details:** The manufacturer or its authorized representative must give notice to the Secretary State of the intended investigation before commencing a clinical trial. The Medical Device Regulations, 16.

**Registration and listing**

**Registration of establishment:** Yes  
**Details:** The manufacturer must inform the Secretary of State with his address and a description of each device. The Medical Device Regulations, 19.  
**Listing of medical devices:** Yes  
**Details:** The manufacturer must inform the Secretary of State with his address and a description of each device. The Medical Device Regulations, 19.

**Import controls**

**Import controls:** N/A  
**Details:** N/A

**Post market controls**

**Post Market Surveillance:** N/A  
**Details:** N/A  
**Inspection (QMS):** Yes  
**Details:** The Secretary of State may arrange for the inspection of—  
(a) any premises occupied, or plant or equipment used, in connection with the carrying out of any such task; or  
(b) any premises occupied, or plant or equipment used, by a manufacturer where the body is undertaking any task in relation to that manufacturer, and may take into account for the purposes of his decision the results of any such inspection and any refusal to afford him such facilities or assistance as he may reasonably require in order to carry out any such inspection.  
The Medical Device Regulations, 45  
**Enforcement:** Yes  
**Details:** The Medical Device Regulations No. 618 (2002), 61

**Adverse event reporting:** Yes  
**Details:** Adverse event reporting is considered to be part of the conformity assessment procedures:  
17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer’s obligations set out in that procedure that apply to him. Medical Device Regulations No.618 (2002), Art. 17  
https://www.gov.uk/guidance/the-yellow-card-scheme-guidance-for-healthcare-professionals

**Field safety corrective action monitoring:** Yes  
**Details:** The Medical Device Regulations No. 618 (2002), 64

**Advertising:** N/A  
**Details:** N/A

**Labelling:** Yes  
**Details:** Labels and other packaging information must be in English for certain devices, while, for others, the label may be in another community language so long as there is a clear state in English that names the language. The Medical Device Regulations, 9.

Limitations: these data reflect a limited view and do not capture what may currently occur within Member States or how they implemented the data. Complete verification of the data may not be immediately possible and inaccuracies may linger. Mis-categorization or non-capture of a country’s regulatory framework is possible due to translation and interpretation.