Malta

Legal
Legal framework: Yes
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Responsibilities of the NRA: Regulatory Affairs Directorate has the responsibility of the transposition and implementation of legislation. Market Surveillance Directorate has the responsibility of ensuring that only goods conforming to regulations are available on the market.

Medical device definition
Medical device defined: Yes
Text: A medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and, or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of -
(a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
(c) investigation, replacement or modification of the anatomy or of a physiological process,
(d) control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. Product Safety Act, Art. 3.

In vitro diagnostic medical device (IVD) defined: Yes
Text: Included, Defined seperately. "in vitro diagnostic medical device" means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:
(a) concerning a physiological or pathological state, or
(b) concerning a congenital abnormality, or
(c) to determine the safety and compatibility with potential recipients, or
(d) to monitor therapeutic measures. Product Safety Act, Art. 3.

Medical device classification
Classification: Yes
Categories: Devices shall be divided into Classes I, IIA, IIB and III. Product Safety Act Art. 2.
Classification rules: Yes
Classification rules details: Product Safety Act, Schedule IX,

Essential principles
Essential principles: Yes
Details: The devices must meet the essential requirements set out in Schedule I which apply to them, taking account of the intended purpose of the devices concerned. Product Safety Act, Art. 5.

Conformity assessment
Conformity assessment bodies: Yes
Details: Regulatory Affairs Directorate
Pre-marketing / procedure: In the case of devices, the manufacturer shall, in order to affix the CE marking: follow the procedure relating to the EC declaration of conformity. Product Safety Act, Art. 6.

Reliance
Reliance: Yes
Details: N/A
Jurisdictions: EU
Clinical investigation
Clinical investigation controls: Yes
Details: In the case of devices intended for clinical investigations to be conducted in Malta, the manufacturer or the authorised representative shall follow the procedure referred to in Schedule VIII and notify the Regulatory Affairs Directorate by means of the statement mentioned in section 2(b) of Schedule VIII. Product Safety Act, Art. 9.

Registration and listing
Registration of establishment: Yes
Details: Any manufacturer who has his registered place of business in Malta and, under his own name, places devices on the market in accordance with the procedures referred to in regulation 6(4) and (5) and any other natural or legal person engaged in the activities referred to in regulation 8(1) to (5) shall inform the Regulatory Affairs Directorate of his registered place of business and the description of the devices concerned. Product Safety Act, Art. 11.
Listing of medical devices: Yes
Details: Any manufacturer who has his registered place of business in Malta and, under his own name, places devices on the market in accordance with the procedures referred to in regulation 6(4) and (5) and any other natural or legal person engaged in the activities referred to in regulation 8(1) to (5) shall inform the Regulatory Affairs Directorate of his registered place of business and the description of the devices concerned. Product Safety Act, Art. 11.

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

Post market controls
Post Market Surveillance: Yes
Details: The aim of surveillance is to ensure that the manufacturer duly fulfil the obligations imposed by the approved quality system. (Schedule II: EC Declaration of Conformity Art. 5)
Inspection (QMS): Yes
Details: The manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with all relevant information Product Safety Act, Schedule III.4
Enforcement: N/A
Details: N/A
Adverse event reporting: Yes
Details: All serious adverse events must be fully recorded and immediately notified to the Market Surveillance Directorate and the Regulatory Affairs Directorate and all competent authorities of the Member States in which the clinical investigation is being performed. Product Safety Act, Schedule X
Field safety corrective action monitoring: Yes
Details: Where it is ascertained that the devices referred to in regulation 5(8) and (9)(b), when correctly installed, maintained and used for their intended purpose, may compromise the health and, or safety of patients, users or, where applicable, other persons, all appropriate interim measures shall be taken by the Director of Market Surveillance to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. Product Safety Act, Art. 10
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of potential users, and to identify the manufacturer. (i) This information comprises the details on the label and the data in the instructions for use. (Schedule I: Essential Requirements Art. 13).

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.