	MDD	MDR
Definition	Not legally binding, the directives are guidelines	These are legally binding regulations Many more terms defined in Article 1 compared to MDD Definition of Device: Added products specifically intended for cleaning, disinfection or sterilization of devices Definition of accessory expanded by adding 'assist', in addition to 'enable'
Classification	Classified as non invasive device Class IIb Surgical meshes may have been categorized as Class IIb All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classifies Class II Software for monitoring physiological processes were Class I No mention of nanomaterial No rule defined for classification of invasive devices to deliver medicinal products by inhalation	Non invasive devices consisting of substance or mixture of substances in contact with human cells, tissues, organs or embryos in vitro before administration or implantation into body to be classifies as Class III Surgical meshes and spinal implants classified as Class III All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classifies Class III Software for monitoring physiological processes were reclassified into Class IIa Classification of nanomaterial from Class IIa to III based on their potential for internal exposure Invasive device to deliver medicinal products by inhalation classifies as Class IIa, unless intended to treat life threatening conditions, in which case they would be classifies as IIb New rule that classifies devices composed of substances or combinations of substances that are to be introduced into the body into classes IIa to III depending on their absorption or dispersion in the body New rule that classifies devices, such as closed loop systems or automated external defibrillators, in Class III
MDCG		Formation of Medical Device Coordination Group comprised of national representatives to foster cooperation between member states, advice Commission, assessment of notified bodies, ensuring effective and harmonized implementation of MDR, contribute to development of device standards
Products without an intended medical purpose	Not covered	Products without an intended medical purpose also brought under the purview of MDR, as mentioned in Annex XVI
Notified Bodies		NBs are allowed to carry out unannounced inspections and physical or laboratory tests on devices Higher scrutiny of high risk devices. NB is obliged to get data on high risk devices assessed by an expert panel
Traceability and transparency		MDR introduces unique device identification (UDI) system to facilitate, transparency, identification and traceability of devices, other than custom made and investigational devices Implant cards provided to patients who receive an implant
Clinical investigation		Various elements, such as, supervision of NB, conformity assessment procedures, clinical investigation and evaluation, vigilance significantly reinforced, times frames established to carry out different assessments and clinical activities A sponsor, not established in the Union, shall designate a legal representative responsible for ensuring compliance Clinical investigation report is to be made publically available on the electronic system Addresses consent forms in detail and clinical investigation carried out in vulnerable population Member states are to ensure that people assessing application do not have any conflict of interest and have the necessary qualification and experience Clinical investigation is designed is such a way that risk to the patient or third person is minimized, as per applicable common specifications or harmonized standards Post-marketing clinical follow-up plan is to be drawn by the sponsor Greater post market surveillance and trend reporting, making the data available on Eudamed Class IIb implantable devices exempt from clinical investigation: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which clinical evaluation is required
Reprocessing		Reprocessing of single use devices allowed only when permitted by national law
Documentation	The manufacturer shall keep technical documentation, EU declaration of conformity and any relevant certificate available for competent authority for a period of 5 years after the last device covered by the EU declaration has been placed on the market and 15 years in case of implantable devices	The manufacturer shall keep technical documentation, EU declaration of conformity and any relevant certificate available for competent authority for a period of 10 years after the last device covered by the EU declaration has been placed on the market and 15 years in case of implantable devices
Legal liability	Manufacturer, suppliers and importers may be legally held responsible for a defective device	When manufacturer is not established in a member state, authorized representative may be held legally liable for a defective device