Regulatory Definitions (as found in the original regulations and interpretation guidelines)

	Australia	Brazil	Canada	EU	Japan	USA
MD definition	Therapeutic Goods Act 1989 (legislation.gov.au) Section 41BD	Medical equipment: Resolution RDC 185/2001 and RDC 40/2015 (Section III Art 3, XXVII) Materials for health use: Resolution RDC 185/2001 and RDC 40/2015 Orthopedic Implants: Resolution RDC 185/2001 In vitro diagnostics: Resolution RDC 36/2015 (Chapter I, Section III Art 3, XXVII)	Food and Drugs Act Section 2 (justice.gc.ca) "device"	MDR Article 2(1) IVDR Article 2(2)	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices(Act No. 145 of 1960) Article 2(4)	Section 321(h)(1) of the Food, Drug & Cosmetic Act
Additional guidelines	Resources | Therapeutic Goods Administration (TGA) (filter to medical devices, search for keyword "defin")	Medical devices — National Health Surveillance Agency - Anvisa (www.gov.br)	Guidance documents – Medical devices - Canada.ca	Guidance - MDCG endorsed documents and other guidance (europa.eu) – see guidelines under the "Borderline and Classification" and "New Technologies" (for software) sections	Regulatory Information | Pharmaceuticals and Medical Devices Agency (pmda.go.jp) Standards for Medical Devices in Japan (pmda.go.jp) (Information criteria for various product groups)	Classify Your Medical Device | FDA (e.g. access-sories)