Device classification based on the applicable regulatory requirements (21 CFR, EU MDR Annex VIII, etc.) and the applicable guidelines:

	Australia	Brazil	Canada	EU	Japan	USA
Classification rules	Therapeutic Goods (Medical Devices) Regulations 2002 (legislation.gov.au) Division 3.1— Medical device classifications, Schedule 2 (MD) and Schedule 2a (IVD)	MD: RDC 751/2022 (Chapter II) IVD: RDC 36/2015 (Chapter II)	Medical Devices Regulations (SOR/98-282) Schedule 1 (justice.gc.ca)	MDR Annex VIII IVDR Annex VIII	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices(Act No. 145 of 1960) Article 2(5)-(8) (defines the classes' names)	FDA Product Classification Database
Additional guidelines	Resources | Therapeutic Goods Administration (TGA) (search for "classification", but there are product group specific guidelines as well)	-	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 and: MDCG 2020-16 Rev.2 for IVD classification	Regulatory Information | Pharmaceuticals and Medical Devices Agency (pmda.go.jp) Standards for Medical Devices in Japan (pmda.go.jp) (MD / IVD > "About Criteria in Regulation / Basic concepts…" shows the mapping between class number and class name and JMDN list shows the class number of each product group)	Classify Your Medical Device | FDA