List of the key-applicable regulations

Name regulation	reference	link	land	Region
EU MDR	REGULATION (EU) 2017/745	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745	Europe	EMEA
EU MDD	DIRECTIVE 93/42/EEC	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31993L0042	Europe	EMEA
UK MDR 2002	UK MDR 2002	https://www.legislation.gov.uk/uksi/2002/618/contents	UK (2021)	EMEA
Ukraine Medical Device Regulation	Technical regulations on medical devices No. 753	https://zakon.rada.gov.ua/laws/show/753-2013-%D0%BF#Text	Ukrain	Direct export
Medical Devices and Supplies Regulation	Royal Decree No.(M/54)	https://laws.boe.gov.sa/BoeLaws/Laws/LawDetails/9daec1bf-6bda-4a65-a111-ace90163af7e/1	Saudi Arabia	Direct export
Medicines and related substances act No. 101 of 1965	Government Gazette No. 40869, 26 May 2017	https://www.sahpra.org.za/wp-content/uploads/2019/09/Medicines-and-Related-Substances-Act_101-of-1965_Act_GG-40869_2017-05-26.pdf	South-Africa	Direct export
Regulations on State (Re-) Registration of Medical devices and Medical Equipment	Resolution 1269 of 02 09 2008 as amended by resolution 273 of 02 05 2019	https://www.rceth.by/en/Departments/Med/Documents?orderby=date&dir=asc	Belarus	Direct export
Code of Federal Regulations	21 CFR Chapter I Subchapter H	21 CFR Part 800-861, 892	USA	NA
Code of Federal Regulations	21 CFR Chapter I Subchapter J	21 CFR Part 1000-1040	USA	NA
Food, Drug & Cosmetic Act	21 U.S.C. Part A - Drugs and Devices	Section 351-360n-1	USA	NA
Food, Drug & Cosmetic Act	21 U.S.C. Part C - Electronic Product Radiation Control	Section 360hh-360ss	USA	NA
Medical Device Regulations	SOR/98-282	Part 1, Sections 8, 10, 21, 25, 26, 28, 32, 33, 34, 44, 52, 57, 59, 63 & Part 4	Canada	NA
Food and Drugs Act	R.S.C 1985, c. F-27	Part I Section 19, Part II	Canada	NA
Radiation Emitting Devices Act	R.S.C. 1985, c. R-1	https://laws-lois.justice.gc.ca/eng/acts/R-1/FullText.html	Canada	NA
FDA Reports of Corrections & Removals	21 CFR 806	CFR - Code of Federal Regulations Title 21	USA	NA
FDA Reports on Accidental Radiation Occurrences	21 CFR 1002	CFR - Code of Federal Regulations Title 21	USA	NA
FDA Medical Device Reporting	21 CFR 803	CFR - Code of Federal Regulations Title 21	USA	NA
HC Distribution Records	MDR SOR/98-282 Section 52 - 56	Medical Devices Regulations	Canada	NA
HC Mandatory Problem Reporting	MDR SOR/98-282 Section 59 - 61	Medical Devices Regulations	Canada	NA
HC Recall	MDR SOR/98-282 Part 1 Section 64 - 65	Medical Devices Regulations	Canada	NA
FDA Establishment Registration & Medical Device Listing	21 CFR Part 807	CFR - Code of Federal Regulations Title 21	USA	NA
FDA PreMarket Notification 510(k)	21 CFR Part 807 SubPart E	CFR - Code of Federal Regulations Title 21	USA	NA
FDA Labeling Requirements	21 CFR Part 801	CFR - Code of Federal Regulations Title 21	USA	NA
HC Licensing Regulations	MDR SOR/98-282 Section 28 - 31	Medical Devices Regulations	Canada	NA
HC Labeling Requirements	MDR SOR/98-282 Section 21 - 23	Medical Devices Regulations	Canada	NA
Overview of supplying therapeutic goods in Australia		https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia#artg	Australia	APSAC
Regulations on the Supervision and Administration of Medical Devices	State Decree No. 739	http://www.gov.cn/zhengce/content/2021-03/18/content_5593739.htm#	China	APSAC
Provisions for Medical Device Registration and filing	Decree No. 47 of China Food and Drug Administration	Decree No. 47	China	APSAC
Provisions for Instructions and Labels of Medical Devices	Decree No. 6 of China Food and Drug Administration	http://english.nmpa.gov.cn/2019-10/11/c_415402.htm	China	APSAC
Provisions for Supervision and Administration of Medical Device Manufacturing	Decree No. 53 of the State Administration for Market Regulation	http://www.gov.cn/gongbao/content/2022/content_5691002.htm	China	APSAC
Provisions for Supervision and Administration of Medical Device Distribution	Decree No. 54 of the State Administration for Market Regulation	http://www.gov.cn/gongbao/content/2022/content_5692860.htm	China	APSAC
Provisions for Administration of Medical Device Recall	Decree No. 29 of the China Food and Drug Administration	http://www.gov.cn/gongbao/content/2017/content_5216439.htm	China	APSAC
Medical Device Adverse Event Monitoring and Reevaluation	State Administration for Market Regulation Oder No.1	https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/fgwj/bmgzh/20180831121501654.html	China	APSAC
Guidance documents for medical devices		https://www.hsa.gov.sg/medical-devices/guidance-documents	Singapore	APSAC
Medical Device Act 2012	Act 737	https://portal.mda.gov.my/documents/regulation/685-medical-device-act-2012-eng/file.html	Malaysia	APSAC
Malaysia Medical device legislation summary		https://portal.mda.gov.my/doc-list/legislation.html	Malaysia	APSAC
India-medical-devices-rules-2017	G.S.R. 78(E)	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=M	India	ASPAC
Amendment - Registration of certain medical devices	G.S.R. 102(E)	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NT	India	ASPAC
Amendment - Warehouse license for medical devices	G.S.R. 754(E)	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/mdsale.pdf	India	ASPAC
Amendment - Registration of Class A (non-sterile and non-r	G.S.R. 777(E)	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=O	India	ASPAC
Medical device regulation of Indonesia		http://regalkes.kemkes.go.id/informasi_alkes/Regulasi%20Lisensi%20Produk.pdf	Indonesia	APSAC
EU GDPR	Regulation (EU) 2016/679	https://eur-lex.europa.eu/eli/reg/2016/679/oj	Europe	EMEA
HIPAA	PUBLIC LAW 104-191	https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996	USA	NA
ANVISA Medical Devices Legislation	Set of legislation for medical devices regularization in Brazil	https://www.gov.br/anvisa/pt-br/assuntos/regulamentacao/legislacao/bibliotecas-tematicas/arquivos/produtos	Brazil	LATAM

Information, Security and Privacy requirements

Requirement	Document link
Follow a Risk Management process in line with ISO 27001:2	N/A
Global Work Instruction - Minimum ISP Requirements for A	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=70485052
Global Guideline RSD - ISP Product Hardening	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=77167070

Information, Security and Privacy deliverables

Deliverable	Document link
Information, Security and Privacy Risk Management Report	N/A
Vulnerability Scan Report	N/A
Manufacturer Disclosure Statement for Medical Device Sec	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=74676036
Global Template - Minimum ISP Requirements for Agfa RSD	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=74726993