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/?	Europe	EMEA
EU MDD	DIRECTIVE 93/42/EEC	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?	Europe	EMEA
UK MDR 2002	UK MDR 2002	https://www.legislation.gov.uk/uksi/2002/618/content	UK (2021)	EMEA
Ukraine Medical Device Regulation	Technical regulations on medical devices No. 753	https://zakon.rada.gov.ua/laws/show/753-2013-%D0%	Ukraine	EMEA
Medical Devices and Supplies Regulation	Royal Decree No.(M/54) dated 6/7/1442 AH	https://laws.boe.gov.sa/BoeLaws/Laws/LawDetails/9da	Saudi Arabia	EMEA
Implementing Regulation of the Law of Medical Devices	SFDA Board Decision No. (3-29-1443) dated 19/02/1443 AH	https://www.sfda.gov.sa/sites/default/files/2023-	Saudi Arabia	EMEA
Regulation related to Medical Devices and In Vitro Diagnostic Medical Devices.	Staatskoerant, 9 Desember 2016 No.40480 61, DoH No.1515:	content/uploads/2024/01/Medical-Device-Regulations-published-9-December-2016-implementation.pdf	South-Africa	EMEA
HSA – Hazardous Substances Act 15 of 1973	HSA – Hazardous Substances Act 15 of 1973 (as amended)	RADIATION CONTROL ACTS AND REGULATIONS - SAHPRA		EMEA
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/Documer	Belarus	EMEA
Resolution On Approval of the Rules for State Registration of medical devices	Resolution of December 27, 2012, No. 1416	resolution_1416.pdf	Russian Federa	EMEA
Agreement on Common Principles and Rules for the Circulation of Medical Devices (Medical Devices and Medical Equipment) within the Eurasian Economic Union	Treaty date of publication 24.12.2014	Circulation of Medical Devices (Medical Devices and Medical Equipment) within the Eurasian Economic	EAEU	EMEA
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, 5	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.ht	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-therapeut	Australia	APSAC
Regulations on the Supervision and Administration of Medical Devices	State Decree No. 739	http://www.gov.cn/zhengce/content/2021-03/18/cont	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_5	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_5	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_5	China	APSAC
Measures for the monitoring and re-evaluation of adverse events of medical devices	Decree No. 1 of the State Administration for Market Regulation and th	https://www.gov.cn/zhengce/2021-06/24/content_572	China	APSAC
Pharmaceutical Affairs Law	Act No.84 of 2013	https://www.mhlw.go.jp/english/policy/health-medica	Japan	ASPAC
Medical Device Act		https://www.mfds.go.kr/eng/brd/m_40/view.do?seq=	South Korea	ASPAC
Guidance documents for medical devices		https://www.hsa.gov.sg/medical-devices/guidance-doc	Singapore	APSAC
Medical Device Act 2012	Act 737	https://portal.mda.gov.my/documents/regulation/685	Malaysia	APSAC
Guidance Document under Medical Device Act 2012 (Act 737)		https://portal.mda.gov.my/index.php/doc-list/guidance	Malaysia	APSAC
Malaysia Medical device legislation summary		https://portal.mda.gov.my/doc-list/legislation.html	Malaysia	APSAC
Medical Devices Act	B.E.2551 (2008) and (No. 2), B.E. 2562 (2019)	https://en.fda.moph.go.th/cat2-health-products/categ	Thailand	APSAC
Medical device regulation of Indonesia		http://regalkes.kemkes.go.id/informasi_alkes/Regulasi	Indonesia	APSAC
Ministry of Health : Detailed regulations on the implementation of a number of Articles of Decree 36	Circular No. 46/2017/TT-BYT dated December 15, 2017	https://dmec.moh.gov.vn/documents/10182/1003059	Vietnam	APSAC
Public Health Law 1972		https://www.moh.gov.mm/file/Law/Public%20Health%	Myanmar	ASPAC
Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administrati	Administrative Order No. 2016-0003	https://www.fda.gov.ph/republic-act/	Philippines	ASPAC
Medical device regulation of Indonesia		http://regalkes.kemkes.go.id/informasi_alkes/Regulasi	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-portabili	USA	NA
ANVISA Medical Devices Legislation	Set of legislation for medical devices regularization in Brazil	https://www.gov.br/anvisa/pt-br/assuntos/regulament	Brazil	LATAM

Information, Security and Privacy requirements

Requirement	Document link
Follow a Risk Management process in line with ISO 27001:2013	N/A
Global Work Instruction - Minimum ISP Requirements for Agfa RSD Solutions and Tools	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 Security (MDS^2)	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=74676036
Global Template - Minimum ISP Requirements for Agfa RSD Solutions and Tools	http://ims-rsd.agfa.net/he/en/intranet/ims/overview.jsp?ID=74726993

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