LINKS RELEVANT FOR MEDICAL DEVICES (MD + IVD) AND RELATED FIELDS

Preface:

The overview shall help the team in charge to better understand where what information may be found, and which sources should be regarded as relevant (at least). The compilation presented reflects some of the sources used by JB in the day-to-day business.

Please note this is a compilation and does not claim to be comprehensive and complete.

Area / #	Title and Coordinates[1]	Short Description	Link(s)
Int'l			
I.1	IMDRF (Int'l Medical Device Regulators Forum) – *(CACoop)*	Int'l Cooperation of MD CAs based on development of Guidelines and their realization via consultation and consensus	http://www.imdrf.org For consultations see: http://www.imdrf.org/consultations/consultations.asp For IVD related info: http://www.imdrf.org/documents/documents.asp
I.2	ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) – *(CACoop)*	Int'l Cooperation of Medicinal CAs based on development of Guidelines and their realization via consultation and consensus	https://www.ich.org For Risk Management (Q9) and Lifecycle Management (Q12) see: https://www.ich.org/page/safety-guidelines For Preclinic see: https://www.ich.org/page/safety-guidelines https://www.ich.org/page/multidisciplinary-guidelines (M3) For "human related aspects": https://www.ich.org/page/efficacy-guidelines
I.3	GMTA (Global Medical Technology Alliance) – *(Association of Nat'l MD Associations)*	Its members are national or regional medical technology associations, which represent innovative companies that currently develop and manufacture 85 percent of the world's medical devices, diagnostics and equipment. It provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs.	http://www.globalmedicaltechnologyalliance.org

[1] Abbr.: **CA**-Competent Authorities; **CACoop**-CA Cooperation; **M** - Ministry; **Dept**.-Part of Ministries; **IAss**.-Industrial Association; **JSA**–Joint Self-Administration; x**SO**-Standardization Organizations.

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I.4	ISO (Int'l Standards Organization Geneva) – *(IAss.)*	Int'l organization of the different regional and national standardization associations located in Geneva, being one of the drivers of technical harmonization.	https://www.iso.org/home.html For Medical Devices see: https://www.iso.org/search.html?q=medical%20devices&hPP=10&idx=all_en&p=0 or https://www.iso.org/ics/11/x/ For IVD see: https://www.iso.org/ics/11.100.10/x/
Region			
R.1	EC - European Commission	General Overview Former Directives New Regulations	https://ec.europa.eu/health/md_sector/overview_en https://ec.europa.eu/health/md_sector/current_directives_en https://ec.europa.eu/health/md_sector/new_regulations_en
R.2	EC - Guidance's	MEDDEV (MDD/IVDD) MDCG (MDR/IVDR)	https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_guidance_meddevs.pdf https://ec.europa.eu/health/md_sector/new_regulations/guidance_en
R.3	Team-NB	NBs Organization	https://www.team-nb.org
R.4	EC - CTR 536/2014 (Clinical Trial Regulation) – Gen. Information linked with EUDAMED	EC Information Page	https://ec.europa.eu/health/human-use/clinical-trials/regulation_en
R.5	MTE (MedTech Europe) – *(IAss)*	Main EU MedTech Ass. List of members Resource library	https://www.medtecheurope.org https://www.medtecheurope.org/about-us/members/ https://www.medtecheurope.org/resource-library/
National			
N.1a	BMG – Bundesministerium der Gesundheit *(M)*	Information on legal activities of DoH	https://www.bundesgesundheitsministerium.de/service/g

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			esetze-und-verordnungen.html
N.1b	BMBF – Bundesministerium für Bildung und Forschung *(M)*	Please note - major contribution „Health Research" – Horizon Europe Follow-up for IMI (Innovative Medicines Initiative)	https://www.bmbf.de https://www.bmbf.de/bmbf/shareddocs/bekanntmachungen/de/2022/04/2022-04-27-Bekanntmachung-Nicht-staatl-Hochschulen.html https://nksg-ihi.ascrion.com/tagesordnung
N.2a	BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte *(CA)*	Federal Institute for Drugs and Medical Devices Training on Clinical Research (series of lecturers updated annually)	https://www.bfarm.de/DE/Home/home_node.html https://www.bfarm.de/DE/Aktuelles/Veranstaltungen/_node.html
N.2b	BfArM Außenstelle Köln (DIMDI) – *(Part of CA)*	Former DIMDI (independent organization initiated by the German government for the information on health topics for the public All MD related aspects	https://www.dimdi.de/dynamic/de/startseite https://www.dimdi.de/dynamic/de/medizinprodukte/
N.2c	PEI – Paul-Ehrlich-Institut Bundesinstitut für Impfstoffe und biomedizinische Impfstoffe *(CA)*	Federal Institute for Vaccines and Biomedicines Surveillance of IVD Legal Test Laboratory	https://www.pei.de/DE/home/home-node.html https://www.pei.de/DE/arzneimittelsicherheit/ivd-vigilanz/ivd-vigilanz-node.html;jsessionid=87983EECD3FC868AA4931B475FF630B3.intranet242 https://www.pei.de/DE/regulation/prueflabor-ivd/prueflabor-ivd-node.html;jsessionid=D4AC6A4A9BC1DE860AFBBFD5E95654BF.intranet211
N3.	ZLG – Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten *(Federal States rel. Admin.)*	Central institution for all regulatory aspects which are related to the Federal States	https://www.zlg.de/zlg

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N.4	RKI – Robert-Koch-Institute *(Inst. controlled by BMG)*	**Our mission** The Robert Koch Institute is Germany's public health institute. "Our mission is to protect and improve the health of the population. To this end, 1,100 individuals from 90 different occupational fields work and conduct research together at RKI every day."	https://www.rki.de/DE/Home/homepage_node.html COVID-Dashboard: https://experience.arcgis.com/experience/478220a4c454480e823b17327b2bf1d4 IGES-COVID Pandemie Monitor: https://www.iges.com/corona/ Health Information – CLL: https://www.rki.de/SiteGlobals/Forms/Suche/serviceSucheForm.html;jsessionid=6A36F96F5A91C185487DD3AB61A28E59.internet082?nn=2725444&resourceId=2390936&input_=2725444&pageLocale=de&searchEngineQueryString=cll&submit.x=0&submit.y=0
N.5	G-BA – Gemeinsamer Bundesausschuss *(JSA)*	The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany. It issues directives for the benefit catalogue of the statutory health insurance funds (GKV) for more than 73 million insured persons and thus specifies which services in medical care are reimbursed by the GKV.	https://www.g-ba.de
N.6	IQWIG - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen *(JSA Support)*	"The independent Institute for Quality and Efficiency in Health Care examines the benefits and harms of medical interventions for patients. We provide information about the advantages and disadvantages of examination and treatment methods in the form of scientific reports and easily understandable health information." Event Presentations	https://www.iqwig.de/ueber-uns/aufgaben-und-ziele/ https://www.iqwig.de/en/events/herbst-symposium/

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N.7	MDS – Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen *(JSA - supporting)*	The MDS is a medical and nursing expert organization that advises statutory health and long-term care insurance at the federal level - in particular the National Association of Statutory Health Insurance Funds. The MDS coordinates the technical work of the MDK in the federal states in order to ensure assessment and advice according to nationwide uniform criteria. Work regarding Reimbursement etc.	https://www.mds-ev.de/der-mds/auf-einen-blick.html https://www.mds-ev.de/richtlinien-publikationen/gutachten-/-nutzenbewertungen-des-mds.html
N.8	InEK – Institut für Entgeltsysteme im Krankenhaus *(JSA)*	For the remuneration of general hospital services, a consistent, performance-oriented and flat-rate remuneration system has been introduced for German hospitals in accordance with Section 17b of the Hospital Financing Act (KHG). The basis for this is the G-DRG system (German-Diagnosis Related Groups-System), whereby every inpatient treatment case is reimbursed by means of a corresponding DRG case flat rate. The tasks related to the introduction, further development and maintenance of the new remuneration system have been assigned to InEK GmbH as the German DRG institute by the self-administration partners in the health sector - the German Hospital Society, the central associations of health insurance companies and the Association of Private Health Insurance. NUB	https://www.g-drg.de https://www.g-drg.de/Neue_Untersuchungs-

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			und Behandlungsmethoden NUB
N.9	Arbeitskreis medizinischer Ethik-Kommissionen für die BRD *(Independent CA-partner required by law and established under administrative law)*	Working group of medical ethics commissions for the FRG providing all information for the preparation of CTA (MD: CEA, PEA)	https://www.akek.de
N.10	AWMF - Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. *(ScAss)*	Association of the Scientific Medical Societies in Germany affiliates 179 Scientific Societies (+ 3 associates) from all specialties of medicine. AWMF represents Germany in the Council for International Organizations of Medical Sciences CIOMS. Clinical Practice Guidelines	https://www.awmf.org/awmf-online-das-portal-der-wissenschaftlichen-medizin/awmf-aktuell.html https://www.awmf.org/leitlinien/aktuelle-leitlinien.html
N.11	VDGH – Verband der Diagnostica-Industrie/LST Life Science Research *(IAss)*	General Info on IVD-Market Marketdata Further background information	https://www.vdgh.de https://www.vdgh.de/marktdaten/deutschland2/diagnostica-markt https://www.vdgh.de/veroeffentlichungen/index
N.12	BVmed – Bundesverbandmedizintechnologie *(IAss)*	Mega homepage with comprehensive information on medical devices and medical tools/aids – very much inland oriented	https://www.bvmed.de
N.13	Spectaris – Deutscher Industrieverband für Optik, Photonik, Analysen- und Medizintechnik *(IAss)*	Broader than BVmed and very export oriented Medical Devices Diagnostics	https://www.spectaris.de https://www.spectaris.de/medizintechnik/ https://www.spectaris.de/analysen-bio-und-labortechnik/
N.14	MDR & IVDR Wegweiser BW	In der Infothek werden relevante Informationen und nützliche Links gebündelt zur Verfügung gestellt **MDR** **IVDR**	https://mdr-ivdr.bio-pro.de/infothek https://mdr-ivdr.bio-pro.de/infothek/mdr

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			https://mdr-ivdr.bio-pro.de/infothek/ivdr
N.15	Medicinal Associations	**VfA** – Verband forschender Arzneimittelhersteller **BPI** – Bundesverband der Pharmazeutischen Industrie **BAH** – Bundesverband der Arzneimittel-Hersteller	https://www.vfa.de https://www.bpi.de/de/ https://www.bah-bonn.de/bah/