MEDICAL DEVICES GUIDANCE SPREADSHEET		
Name of Webpage	**Description**	**Website Address**
MDCG (Medical Device Coordination Group)	The Medical Device Coordination Group (MDCG) deals with key issues from the medical devices sector. Its expertise originates from its division into 13 subgroups, which respectively provide advice and draft guidance on their expertise field. The members of the subgroups are appointed by the Member States for a duration of 3 years. Stakeholders/European-based associations participate in the meetings following applications to dedicated calls for expression of interest. They meet regularly with the EU Commission as Chair. The 13 sub-groups are: 1. Notified Bodies Oversight 2. Standards 3. Clinical Investigation and Evaluation 4. Post-Market Surveillance and Vigilance 5. Market Surveillance (relevant for Competent Authorities only) 6. Borderline and Classification 7. New Technologies 8. EUDAMED 9. Unique Device Identification (UDI) 10. International Matters 11. In Vitro Diagnostic Medical Devices (IVDs) 12. Nomenclature 13. "Annex XVI" Products	Guidance - MDCG endorsed documents and other guidance (europa.eu)
MEDDEV (MEDical DEVice Documents)	The MEDDEV Guidance Documents were developed by various working groups on behalf of the European Commission to assist stakeholders in implementing directives related to medical devices. They were specifically written for the MDD/AIMD/IVDD so are not generally applicable to the MDR/IVDR, however in some areas (e.g., Clinical Evaluation and Vigilance) due to the present lack of MDCG guidance these are considered the best guidance documents avaialble and are therefore still used with the MDR/IVDR.	md_guidance_meddevs_0.pdf (europa.eu)

NANDO (New Approach Notified and Designated Organisations)	NANDO is published and maintained by the EU Commission, it is an electronic register of all designated Notified Bodies for all directives/regulations under the control of the EU. There are separate registers for MDR and IVDR.	Overall legislation (includes MDR, IVDR, MDD, AIMD, IVDD): EUROPA – European Commission – Growth – Regulatory policy - SMCS
Competent Authority List	RAPS website detailing contact details for all European (not just EU) Competent Authorities for Medical Devices and Medicines.	The Essential List of Regulatory Authorities in Europe | RAPS
CAMD (Competent Authorities for Medical Devices)	The Competent Authorities for Medical Devices (CAMD) facilitates implementing and enforcing the Regulations on medical devices and In Vitro Diagnostic medical devices. The CAMD also provides training and exchange of best practices. The webpage is mainly password-controlled but there is public access to the MDR/IVDR Implementation section. Specifically documents on FAQs (Frequently Asked Questions) is on main interest	CAMD - Competent Authorities for Medical Devices : CAMD (camd-europe.eu)
Team-NB (The European Association Medical devices of Notified Bodies)	Trade Association of Notified Bodies presently with 42 members, voluntary organization which endeavours to set good practices and quality for Notified Bodies. Again, password-controlled website but access to public areas, with documents from: 1. NBCG-Med (Notified Body Coordination Group) - Drafts technical recommendations and creates consensus on matters relating to conformity assessment and the activities of notified bodies. Documents include NB-Med documents which like MEDDEVs were written for MDD/AIMD/IVDD but still useful for MDR/IVDR (*Note: on website NBM documents = MDR/IVDR & NB-Med documents = MDD/AIMD/IVDD documents). 2. Team-NB documents, consensus documents on different issues agreed by all members. Separate tabs on the Home page give access to documents.	Home - Welcome to Team NB | Team NB (team-nb.org)

NBO/NBOG (Notified Bodies Oversight/Notified Bodies Operation Group)	The same body changed its name from NBOG to NBO when MDR/IVDR became law. The group shares experiences and exchanges views on issues relating to notified bodies and the application of conformity assessment procedures with the aim of a consistent application of requirements and procedures. It drafts technical recommendations on matters relating to notified bodies and conformity assessment. At the EU Commission's request, it provides advice in matters concerning the coordination group of notified bodies	NBOG Documents
EU Commission - Medical Devices Sector	Home page of EU Commissions webpage on the medical devices sector, contains latest updates and highlights	Medical Devices - Sector (europa.eu)
EU-Commission - Legislation	EU Commission page on information on both MDR & IVDR Legislation and Extensions as well as Implementing Regulations and Delegated Acts.	New Regulations (europa.eu)
EU Commission - EUDAMED	EU Commission page on information and the use of the EUDAMED database	Medical Devices - EUDAMED (europa.eu)
EU Commission - Unique device Identifier (UDI) Requirements	EU Commission page on information on EU UDI requirements Includes information on the 4 x issuing entities and their formats	Unique Device Identifier - UDI (europa.eu)
EU Commission - EMDN (European Medical Device Nomenclature)	EU Commission page on details of the EMDN and link to the latest version of the EMDN	European Medical Device Nomenclature (EMDN) (europa.eu)
EU Commission - MDR Harmonized Standards	EU Commission page on Harmonized Standards - Separate pages for MDR & IVDR.	1. MDR: DocsRoom - European Commission (europa.eu)
EU Commission - MDR Harmonized Standards	EU Commission page on Harmonized Standards - Separate pages for MDR & IVDR.	2. IVDR: DocsRoom - European Commission (europa.eu)
EU Commission - Consensus Statements	Consensus statements are additional guidance documents issued by the EU Commission	md_consensus_statements_0.pdf (europa.eu)
IMDRF (International Medical Device Regulators Forum)	A global network of regulators that aims to promote an efficient and effective regulatory model for medical devices. IMDRF has guidance documents on numerous technical areas. These documents are used by regulators worldwide when producing their local regulations (the EU and UK are full members and participate in workshops that produce the documents). See the documents tab on the home page.	International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum

GHTF (Global Harmonization Task Force)	Predecessor of IMDRF, also produced documents which are either still standalone documents or are the basis of later IMDRF Documents. GHTF documents are maintained in the "documents tab" of the GHTF website	International Medical Device Regulators Forum (IMDRF) | International Medical Device Regulators Forum
MedTech	Trade Association of European Medical Device Companies. The website has Press Releases, Blogs, and Podcasts on various issues relating to regulatory requirements in Europe and worldwide.	About us - MedTech Europe, from diagnosis to cure