**Non limitative overview of EU product / substance legislation relevant to medical devices manufacturers**

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| **Regulation/Directive** | **Short Description** | **Link** | **Remarks** | **Responsible Agency** | **Summary of Legislation** |
| Reg 1907/2006/EC | REACH Regulation, basis document | [Regulation 1907/2006](http://eur-lex.europa.eu/Notice.do?val=444402:cs&lang=en&list=516890:cs,516899:cs,515837:cs,488164:cs,471644:cs,449533:cs,444402:cs,&pos=7&page=1&nbl=7&pgs=10&hwords=) | Scope: article 5, 6, 60, 62 | [European Chemicals Agency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm) |
| Reg 143/2011/EU | REACH Regulation, 1st amending Annex XIV | [Regulation 143/2011](http://eur-lex.europa.eu/Notice.do?val=560187:cs&lang=en&list=560463:cs,560187:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=) | Exemption for DEHP, DBP, BBP | [European Chemicals Agency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm)  |
| Reg 125/2012/EU | REACH Regulation, 2nd amending Annex XIV | [Regulation 125/2012](http://eur-lex.europa.eu/Notice.do?val=647445:cs&lang=en&list=647445:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | i.a. substances added to Annex XIV (Lead chromates, Arsenic-containing flame retardants) | [European Chemicals Agency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm) |
| Reg 494/2011/EU | REACH Regulation, amended | [Regulation 494/2011](http://eur-lex.europa.eu/Notice.do?val=573231:cs&lang=en&list=680237:cs,573231:cs,572982:cs,&pos=2&page=1&nbl=3&pgs=10&hwords=) | Regulates use of Cadmium | [European Chemicals Agency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm) |
| Reg 835/2012/EU | REACH Regulation, amended | [Regulation 835/2012](http://eur-lex.europa.eu/Notice.do?val=688801:cs&lang=en&list=688801:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Regulates Cadmium (additional)  | [European ChemicalsAgency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm) |
| Reg 836/2012/EU | REACH Regulation, amended | [Regulation 836/2012](http://eur-lex.europa.eu/Notice.do?val=688781:cs&lang=en&list=688781:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Regulates Lead  | [European Chemicals Agency](http://echa.europa.eu/) | [REACH-Chemicals](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21282_en.htm) |
| Reg 1272/2008/EC | REACH Regulation, amended EU-CLP | [Regulation 1272/2008](http://eur-lex.europa.eu/Notice.do?val=486098:cs&lang=en&list=555563:cs,555564:cs,555566:cs,555559:cs,555561:cs,490877:cs,486098:cs,&pos=7&page=1&nbl=7&pgs=10&hwords=) | Labeling - transport of hazardous substances. Scope: article 1 (5) | [European Commission-Dangerous Substances](http://ec.europa.eu/environment/archives/dansub/home_en.htm) | [Labeling/Packaging of Hazardous Substances](http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/l21273_en.htm) |
| Dir 2011/65/EU | RoHS II – electron(on)ic app. | [Directive 2011/65/EC](http://eur-lex.europa.eu/Notice.do?val=576071:cs&lang=en&list=684546:cs,576071:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=) | Restriction of hazardous substances in products (heavy metals, etc.). Article 2: not for active implants. Applicable from 22 July 2014 (Article 4 (1) (3))Annex IV: exempts medical devices. | [Hazardous substances in electronics](http://ec.europa.eu/environment/waste/rohs_eee/legis_en.htm) | [Electronic Waste](http://europa.eu/legislation_summaries/environment/waste_management/l21210_en.htm) |
| Dir 2012/19/EC | WEEE II - electr(on)ic waste | [Directive 2012/19/EC](http://eur-lex.europa.eu/Notice.do?val=682081:cs&lang=en&list=682081:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Waste from electrical and electronic equipment. .From 13 August 2012 to 14 August 2018 applicable to medical devices (with the exception of all implanted and infected products). Scope: article 2. | [European Commission-Waste](http://ec.europa.eu/environment/waste/weee/index_en.htm) | [Electronic Waste](http://europa.eu/legislation_summaries/environment/waste_management/l21210_en.htm) |
| Reg 10/2011/EU | EU Food packaging | [Regulation 10/2011](http://eur-lex.europa.eu/Notice.do?val=555145:cs&lang=en&list=621879:cs,625633:cs,625620:cs,621870:cs,571549:cs,555145:cs,&pos=6&page=1&nbl=6&pgs=10&hwords=)[Regulation 1183/2012](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32012R1183:EN:NOT) | See also EMA packaging guideline, replaces Dir 2002/72/EC | [European Commission-Food Packaging](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm) | [Plastic Materials/Articles in contact with Food](http://europa.eu/legislation_summaries/food_safety/contamination_environmental_factors/sa0028_en.htm) |
| Reg 2023/2006/EC | EU GMPs for materials and articles intended to come into contact with food | [Regulation 2023/2006](http://eur-lex.europa.eu/Notice.do?val=438359:cs&lang=en&list=438359:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | See also EMA packaging guideline | [European Commission-Food Packaging](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm) | [Food Packaging GMP](http://europa.eu/legislation_summaries/food_safety/contamination_environmental_factors/l12076_en.htm) |
| Reg 1935/2004/EC | EU Food packaging materials, objects | [Regulation 1935/2004](http://eur-lex.europa.eu/Notice.do?val=391318:cs&lang=en&list=391318:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Materials and articles, includingactive and intelligent food contact materials and articles. | [European Commission-Food Packaging](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/legisl_list_en.htm) | [Food Packaging, Materials and Objects](http://europa.eu/legislation_summaries/food_safety/contamination_environmental_factors/l21082a_en.htm) |
| Dir 94/62/EC | EU Packaging & Packaging Waste | [Directive 94/62](http://eur-lex.europa.eu/Notice.do?val=302037:cs&lang=en&list=302037:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Management of packaging and packaging waste | [European Commission-Packaging](http://ec.europa.eu/environment/waste/packaging_index.htm) | [Packaging and Packaging Waste](http://europa.eu/legislation_summaries/environment/waste_management/l21207_en.htm) |
| Dir 2010/32/EC | Prevention from sharp injuries in the hospital and healthcare sector | [Directive 2010/32](http://eur-lex.europa.eu/Notice.do?val=516777:cs&lang=en&list=516777:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Annex: Clause 6 and 8 specifically mention medical devices. | [European Agency for Safety and Health at work](https://osha.europa.eu/en/front-page/view) | [Prevention from sharp injuries](https://osha.europa.eu/en/legislation/directives/sector-specific-and-worker-related-provisions/osh-directives/council-directive-2010-32-eu-prevention-from-sharp-injuries-in-the-hospital-and-healthcare-sector) |
| National telecommunications rules | Allocation of broadcast frequencies for medical devices | [Telecommunicatiewet](http://wetten.overheid.nl/BWBR0009950/volledig/geldigheidsdatum_07-12-2012#Hoofdstuk10) |  | [Authority for Consumers and Markets](https://www.acm.nl/en/) (NL) |  |
| Dir 1999/5/EC | R&TTE | [Directive 1999/5](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF) | Radio and telecommunications and terminal equipment | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/rtte/index_en.htm) | [Radio and telecommunications terminal equipment](http://europa.eu/legislation_summaries/consumers/consumer_safety/l21003a_en.htm) |
| Dir 2009/125/EC and Dir 2010/30/EU | EuP | [Directive 2009/125](http://eur-lex.europa.eu/Notice.do?val=503353:cs&lang=en&list=503353:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) and[Directive 2010/30](http://eur-lex.europa.eu/Notice.do?val=517716:cs&lang=en&list=517716:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Energy using Products. i.a. Ecodesign requirements, labelling and standard product information | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/index_en.htm) | [Ecodesign](http://europa.eu/legislation_summaries/energy/energy_efficiency/en0018_en.htm)[Information and labelling](http://europa.eu/legislation_summaries/energy/energy_efficiency/en0022_en.htm) |
| Dir 2001/83/EC | Medicinal Products | [Directive 2001/83](http://eur-lex.europa.eu/Notice.do?val=261620:cs&lang=en&list=676148:cs,432478:cs,261620:cs,&pos=3&page=1&nbl=3&pgs=10&hwords=) | Borderline between medicinal products and medical devices, combined products. See article 1 (4a) and article 3. | [European Commission-Medicinal Products for Human Use](http://ec.europa.eu/health/human-use/index_en.htm) | [Medicinal Products for Human Use](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/l21230_en.htm) |
| Reg 1394/2007/EC | Advanced Therapy Medicinal Products | [Regulation 1394/2007](http://eur-lex.europa.eu/Notice.do?val=461284:cs&lang=en&list=492478:cs,461284:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=) | Contains regime for combined ATMP-device products. See also recitals 4, 6, 14 and 18 of the Regulation.  | [EMA](http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000294.jsp&mid=WC0b01ac05800241e0) | [Advanced Therapy Medicinal Products](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/l21212_en.htm) |
| Dir 2004/23/EC | Setting standards of quality and safety for the donation, procurement, testing, processing,preservation, storage and distribution of human tissues and cells | [Directive 2004/23](http://eur-lex.europa.eu/Notice.do?val=343286:cs&lang=en&list=343286:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Contains requirements for transport and donations of cells and tissue (devices processing cells/tissue) See also recital 6 of the Directive. |  | [Tissues and cells directive](http://europa.eu/legislation_summaries/public_health/threats_to_health/c11573_en.htm) |
| Reg 722/2012/EU | Active implantable medical devices and medical devices manufactured utilizing tissues of animal origin | [Regulation 722/2012](http://eur-lex.europa.eu/Notice.do?val=686864:cs&lang=en&list=686864:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Requirements with respect to active implantable medical devices and medical devices manufactured utilizing tissues of animal origin | [European Commission Health and Consumers](http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm) |  |
| Reg 142/2011/EU | Health rules for animal by-products | [Regulation 142/2011](http://eur-lex.europa.eu/Notice.do?val=560531:cs&lang=en&list=578887:cs,578898:cs,575100:cs,560531:cs,&pos=4&page=1&nbl=4&pgs=10&hwords=) | Health rules as regards animal by-products and derived products not intended for human consumption. For medical devices see recital 30 and article 26. | [European Commission Health and Consumers](http://ec.europa.eu/food/food/biosafety/animalbyproducts/index_en.htm#rules) |  |
| Dir 2007/46/EC | Ambulances – EC type-approval system for motor vehicles | [Directive 2007/46](http://eur-lex.europa.eu/Notice.do?val=456852:cs&lang=en&list=678672:cs,507208:cs,505128:cs,456852:cs,&pos=4&page=1&nbl=4&pgs=10&hwords=) | List of regulatory acts setting the requirements for the purpose of EC type-approval of special purpose vehicles (Annex XI, appendix I) | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/automotive/index_en.htm) | [Approval system](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/motor_vehicles/motor_vehicles_technical_harmonisation/n26100_en.htm) |
| Dir 96/44/EC | Motor vehicles – adapting to technical progress | [Directive 96/44](http://eur-lex.europa.eu/Notice.do?val=344391:cs&lang=en&list=344391:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Measures to be taken against air pollution | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/automotive/documents/directives/motor-vehicles/index_en.htm) |  |
| Dir 98/8/EC | Placing on the market of biocidal products | [Directive 98/8](http://eur-lex.europa.eu/Notice.do?val=226476:cs&lang=en&list=273869:cs,226476:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=)[Regulation 528/2012](http://eur-lex.europa.eu/Result.do?T1=V1&T2=2012&T3=528&RechType=RECH_naturel&Submit=Search) | Directive 98/8: Article 1 (g), (h) exclude medical devices.Regulation 528/2012/EC concerning the making available on the market and use of biocidal products enters into force Sept 1, 2013.  | [European Commission-Biocides](http://ec.europa.eu/environment/biocides/) | [Regulation 528/2012](http://europa.eu/legislation_summaries/food_safety/plant_health_checks/sa0030_en.htm) |
| Dir 95/46/EC | Privacy / data protectionClinical data and other personal data | [Directive 95/46](http://eur-lex.europa.eu/Notice.do?val=307229:cs&lang=en&list=307229:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | [New proposal released Jan 25, 2012](http://ec.europa.eu/justice/data-protection/minisite/)  | [European Commission Justice](http://ec.europa.eu/justice/newsroom/data-protection/) | [Protection of personal data](http://europa.eu/legislation_summaries/information_society/data_protection/l14012_en.htm) |
| Reg 207/2012/EU | Requirements electronic instructions for use of medical devices  | [Regulation 207/2012](http://eur-lex.europa.eu/Notice.do?val=649639:cs&lang=en&list=649639:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | In force since March 1, 2013. This Regulation establishes the conditions under which the instructions for use of medical devices referred to in point 15 of Annex 1 to Directive 90/385/EEC and in point 13 of Annex I to Directive 93/42/EEC may be provided in electronic form instead of in paper form. |  |  |
| Dir 85/374/EC | Liability for defective products | [Directive 85/374](http://eur-lex.europa.eu/Result.do?T1=V3&T2=1985&T3=374&RechType=RECH_naturel&Submit=Search) | No/fault liability | [European Commission Health and Consumers](http://ec.europa.eu/consumers/index_en.htm) | [Liability defective products](http://europa.eu/legislation_summaries/consumers/consumer_safety/l32012_en.htm) |
| Dir 2001/95/EC | General Product safety and liability | [Directive 2001/95](http://eur-lex.europa.eu/Notice.do?val=272287:cs&lang=en&list=272287:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Product safety and market surveillance rules | [European Commission Health and Consumers](http://ec.europa.eu/consumers/index_en.htm) | [General rules product safety](http://europa.eu/legislation_summaries/consumers/consumer_safety/l21253_en.htm) |
| Dir 2006/66/EC | Battery | [Directive 2006/66](http://eur-lex.europa.eu/Notice.do?val=433535:cs&lang=en&list=449551:cs,449550:cs,436788:cs,435685:cs,433535:cs,&pos=5&page=1&nbl=5&pgs=10&hwords=) | Requirements for design/disposal of batteries. Prohibition of portable batteries that contain more than 0,002 % ofcadmium by weight Medical equipment is exempted from the scope in article 4.  | [European Commission Environment](http://ec.europa.eu/environment/waste/batteries/index.htm) | [Disposal of spent batteries](http://europa.eu/legislation_summaries/environment/waste_management/l21202_en.htm) |
| Dir 1999/93/EC | Electronic signatures | [Directive 1999/93](http://eur-lex.europa.eu/Notice.do?val=335272:cs&lang=en&list=337362:cs,335272:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=) |  |  |  |
| Dir 2004/108/EC | Electromagnetic compatibility (EMC) | [Directive 2004/108](http://eur-lex.europa.eu/Notice.do?val=392911:cs&lang=en&list=392911:cs,&pos=1&page=1&nbl=1&pgs=10&hwords=) | Medical devices. Equipment within the scope of Directive 1999/5/EC is exempted in article 1.  | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/electrical/emc/) | [EMC](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/electromagnetic-compatibility/index_en.htm) |
| Dir 89/686/EEC | Personal protective equipment | [Directive 89/686](http://eur-lex.europa.eu/Notice.do?val=548424:cs&lang=en&list=548424:cs,465556:cs,149778:cs,&pos=1&page=1&nbl=3&pgs=10&hwords=) | Rules concerning placing on the market of PPE. Excluded products in Annex I. See also the [interpretative document](http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_ppe_2009_en.pdf) for ‘dual purpose’ devices. |  | [Mechanical engineering](http://ec.europa.eu/enterprise/sectors/mechanical/personal-protective-equipment/index_en.htm) |
| Reg 1223/2009/EC | Cosmetics | [Regulation 1223/2009](http://eur-lex.europa.eu/Notice.do?val=505838:cs&lang=en&list=691485:cs,691488:cs,525784:cs,505838:cs,&pos=4&page=1&nbl=4&pgs=10&hwords=) | Entry into force 11 July, 2013. Medical devices are exempted from the scope of this Directive. See recital 6. | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/chemicals/documents/specific-chemicals/laboratory-practice/cosmetics_en.htm) | [Cosmetic products](http://europa.eu/legislation_summaries/consumers/consumer_safety/co0013_en.htm) |
| Dir 2006/42/EC | Machinery directive. Essential health and safety requirements. | [Directive 2006/42](http://eur-lex.europa.eu/Notice.do?val=427745:cs&lang=en&list=572047:cs,451567:cs,445826:cs,444735:cs,427745:cs,&pos=5&page=1&nbl=5&pgs=10&hwords=) | Medical devices can qualify as ´machinery´. See also requirement 1.7.4.2. in Annex I concerning effect on medical devices and the [interpretative document](http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_machinery_2009_en.pdf) on medical devices that qualify as machinery. | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/machinery/index_en.htm) | [Mechanical engineering](http://ec.europa.eu/enterprise/sectors/mechanical/documents/legislation/machinery/)[Guide](http://ec.europa.eu/enterprise/sectors/mechanical/files/machinery/guide-appl-2006-42-ec-2nd-201006_en.pdf)  |
| Dir 97/23/EC | Pressure Vessels | [Directive 97/23](http://eur-lex.europa.eu/Notice.do?val=218515:cs&lang=en&list=569129:cs,569097:cs,234309:cs,218516:cs,218515:cs,&pos=5&page=1&nbl=5&pgs=10&hwords=) | Medical devices with a pressure vessel up to 200 bar and a volume of less than 1 liter or at a pressure above 0.5 bar and vessels with a volume greater than 1 litera pressure / volume product P x V = to <25 bar.l, do not have to be reviewed by a Notified Body (NB) under this regulation, but, in case of medical devices of Class IIa and higher, have to be reviewed by the NB under the 93/42 on safety, functionality, risk incidents and misuse. | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/pressure-and-gas/documents/ped/index_en.htm) | [Pressure equipment](http://europa.eu/legislation_summaries/consumers/consumer_safety/l21018_en.htm) |
| Commission Recommendation 2003/361/EC | Definitions SMEs | [Recommendation 6 May 2003](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF) | Benefits for SME’s under ATMP and Regulation 726/2004 (medicinal products) | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/) | [Definition SME](http://ec.europa.eu/enterprise/policies/sme/files/sme_definition/sme_user_guide_en.pdf) |
| Dir 2001/18/EC | Safety for audio, video and ICT, food contact safety plastics, functional chemicals | [Directive 2001/18](http://eur-lex.europa.eu/Notice.do?val=259193:cs&lang=en&list=285001:cs,259193:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=) | Deliberate release into the environment of GMOs |  | [Deliberate release GMOs](http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l28130_en.htm) |
| Dir 2005/84/EC | Toys and childcare articles – restriction of phthalates | [Directive 2005/84](http://eur-lex.europa.eu/Notice.do?val=419604:cs&lang=en&list=423139:cs,421700:cs,419604:cs,&pos=3&page=1&nbl=3&pgs=10&hwords=) | Medical devices combined with toys. | [European Commission Enterprise and Industry](http://ec.europa.eu/enterprise/sectors/toys/safety/) | [Phthalate-containing soft PVC toys and childcare articles](http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/technical_harmonisation/l32033_en.htm)  |
| COM (2011) 348 New proposal released June 14, 2012  | Exposure of workers to electromagnetic fields | [Directive 2004/40/EC](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:159:0001:0026:EN:PDF) | Relevant for imaging device manufacturers |  | [Exposure to electromagnetic fields](http://europa.eu/legislation_summaries/public_health/health_determinants_environment/c11150_en.htm) |

<http://tiny.cc/jma1vw>