EU 指令(CE Marking)と整合規格(Harmonized Standards)

ーOfficial Journal(EU 官報)により、現在の各指令の整合規格を確認するー

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

(1) 機械指令 (MD:Machinery Directive) 2006/42/EC

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/machinery_en

1) MD 指令 (PDF) *2014/3/29 (2008/42/EC: M4)

DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast)

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006L0042:LATEST:EN:PDF

2) 整合規格 (PDF) *2016/9/9

Commission communication in the framework of the implementation of the Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC (recast)

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0909(04)&from=EN

3) ガイダンス

・Guidance on CE marking for professionals

https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

・Guide to application of the Machinery Directive 2006/42/EC *Edition 2.1 – July 2017 (Update of 2nd Edition)

http://ec.europa.eu/docsroom/documents/24722

(2) 低電圧指令 (LVD:Low Voltage Directive) 2014/35/EU

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/low-voltage_en

1) LV指令 (PDF) *2014/3/29

DIRECTIVE 2014/35/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014on the harmonization of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (recast)

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0035&from=EN

2) 整合規格 (PDF) *2018/9/14

Commission communication in the framework of the implementation of Directive 2014/35/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2018_326_R_0002&from=EN

3) ガイダンス

・Guidance on CE marking for professionals

https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

・Guide to application of the Low Voltage Directive 2014/35/EU

https://ec.europa.eu/growth/sectors/electrical-engineering/lvd-directive_en

・LOW VOLAGE DIRECTIVE 2014/35/EU GUIDELINES *August 2018

Electrical equipment designed for use within certain voltage limits

http://ec.europa.eu/DocsRoom/documents/31221

・Guidance document on the Low Voltage Directive transition from 2006/95/EC to 2014/35/EU *2015/10/15

http://ec.europa.eu/DocsRoom/documents/13141/attachments/1/translations

(3) EMC指令 (EMCD：EMC Directive)　2014/30/EU

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/electromagnetic-compatibility_en

1) EMC指令（PDF）*2014/3/19

DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast)

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0030&from=EN

2) 整合規格（PDF） *2018/7/13

Commission communication in the framework of the implementation of Directive 2014/30/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to electromagnetic compatibility

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018XC0713(02)&from=EN

3) ガイダンス

・Guidance on CE marking for professionals

https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

・Guide for the EMCD (Directive 2014/30/EU)　*March 2018

https://ec.europa.eu/docsroom/documents/28323

・Guidance document on the EMCD transition from 2004/108/EC to 2014/30/EU　*2016/4/29

http://ec.europa.eu/DocsRoom/documents/16511

(4) RE指令 (RED：Radio Equipment　Directive)　2014/53/EU

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/red_en

1) RE指令（PDF） *2014/5/22

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0053&from=EN

2) 整合規格（PDF） *2018/9/14

Commission communication in the framework of the implementation of Directive 1999/5/EC of the European Parliament and of the Council on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and Directive 2014/53/EU of the European Parliament and of the Council on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2018_326_R_0004&from=EN

3) ガイダンス

・Guidance on CE marking for professionals

https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

・Guide to the Radio Equipment Directive 2014/53/EU　*Version of 05 June 2018

https://ec.europa.eu/docsroom/documents/29782

・FAQs – Radio Equipment Directive (RE-D)　*2017/4/26

http://ec.europa.eu/DocsRoom/documents/24921

(5) RoHS指令 (RoHS：RoHS Directive) 2011/65/EU

Restriction of the use of certain hazardous substances (RoHS)
https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/restriction-of-hazardous-substances_en

1) RoHS指令 (PDF) *2011/7/1

DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0065&from=EN

2) 整合規格 (PDF) *2012/11/23

Commission communication in the framework of the implementation of Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:363:0006:0007:EN:PDF

3) ガイダンス *History of the RoHS Recast

http://ec.europa.eu/environment/waste/rohs_eee/

(6) MDD指令 (MDD：Medical Device Directive) 93/42/EEC

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

1) MDD指令 (PDF) *2007/9/21(M5)

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
Amended by: Official Journal / No page date
►M1 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 / L 331 1 7.12.1998
►M2 Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 / L 313 22 13.12.2000
►M3 Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 / L 6 50 10.1.2002
►M4 Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 / L 284 1 31.10.2003
►M5 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 / L 247 21 21.9.2007
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF

2) 整合規格 (PDF) *2017/11/7

Commission communication in the framework of the implementation of the Council Directive 93/ 42/EEC concerning medical devices
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOC_2017_389_R_0003&from=EN

3) ガイダンス

・Guidance on CE marking for professionals
https://ec.europa.eu/growth/single-market/ce-marking/manufacturers

・Guidance related to medical devices directives
The European Commission provides a range of guidance documents to assist stakeholders in implementing directives related to medical devices. *With MDCG documents, Guidance MEDDEVs, Consensus statements, Informative document.
https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

(7) IVD指令 (IVDD：In Vitro Diagnostic medical Devices Directive) 98/79/EC

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

1) IVDD指令 (PDF) *1998/12/7

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31998L0079&from=EN

2) 整合規格 (PDF) *2017/11/17

Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=uriserv:OJ.C_.2017.389.01.0062.01.ENG

3) ガイダンス

・Guidance on CE marking for professionals

https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en

・Guidance related to medical devices directives

The European Commission provides a range of guidance documents to assist stakeholders in implementing directives related to medical devices. *With MDCG documents, Guidance MEDDEVs, Consensus statements, Informative document.

https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

(8) 医療機器規則 (MDR/IVDR)

・欧州埋込型能動医用機器指令, AIMD(90/385/EEC)
・欧州医療機器指令, MDD(93/42/EEC)
・欧州体外診断医療機器指令, IVDD(98/79/EC)

→

Medical Device Regulation (MDR)
In Vitro Diagnostics Regulation (IVDR)

・医療機器指令(MDD)から医療機器規則(MDR)へ *(独法)東京都立産業技術研究センター

https://www.iri-tokyo.jp/book/list/book25.html