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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Draft DECISION OF THE EU-MONACO JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE PRINCIPALITY OF MONACO ON THE APPLICATION OF CERTAIN COMMUNITY ACTS ON THE TERRITORY OF THE PRINCIPALITY OF MONACO amending the Annex to that Agreement

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DECISION NO …/… OF THE EU-MONACO JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT BETWEEN THE EUROPEAN COMMUNITY AND THE PRINCIPALITY OF MONACO ON THE APPLICATION OF CERTAIN COMMUNITY ACTS ON THE TERRITORY OF THE PRINCIPALITY OF MONACO

of …

amending the Annex to that Agreement

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco[1] (the 'Agreement'), and in particular Article 1(1) thereof,

[1] OJ L 332, 19.12.2003, p. 42, ELI: http://data.europa.eu/eli/agree_internation/2003/885/oj.

Whereas:

(1) The Annex to the Agreement was last amended by Decision No 1/2013 of the EU-Monaco Joint Committee[2] established by the Agreement (the 'Joint Committee'). Since the adoption of that Decision, the Union has undertaken a reform of Union legislation concerning health products, including a fundamental revision of the rules on medical devices and *in vitro* diagnostic medical devices, in order to establish a robust regulatory framework to ensure a high level of safety and health protection.

(2) A decision of the Joint Committee (the 'Joint Committee Decision') is therefore necessary to amend the Annex to the Agreement to include the new Union acts concerning health products, including medical devices and *in vitro* diagnostic medical devices.

(3) The Joint Committee Decision should also address certain difficulties encountered in the conduct of joint inspections by the Monegasque and French authorities of laboratories and production facilities established in the Principality of Monaco.

[2] OJ L 279, 19.10.2013, p. 73, ELI: http://data.europa.eu/eli/dec/2013/513/oj.

(4) The Joint Committee Decision should not extend the scope of the Agreement nor should it create any additional rights beyond those arising under the Agreement.

(5) It is recalled that, pursuant to Article 1(2) of the Agreement, acts of the European Commission adopted in application of the acts listed in the Annex to the Agreement apply on the territory of the Principality of Monaco without the need for a decision of the Joint Committee,

HAS ADOPTED THIS DECISION:

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Article 1

The text set out in the Annex to the Agreement is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the day of its adoption.

Done at …, …

For the Joint Committee
The Chair
Head of the delegation of …
The Secretaries

PUBLIC

ANNEX

‘ANNEX

I. MEDICINES

ACTS REFERRED TO

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67), as amended by:

   – Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC (OJ L 157, 20.6.2023, p. 1);

   – Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (OJ L 118, 20.4.2022, p. 4);

   – Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241);

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– Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24);

– Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

– Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 238, 16.9.2017, p. 44);

– Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1);

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– Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74);

– Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74);

– Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (OJ L 242, 15.9.2009, p. 3);

– Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33);

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– Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission (OJ L 81, 20.3.2008, p. 51);

– Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121);

– Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1);

– Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34);

– Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 85);

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– Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46);

– Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1), as amended by:

– Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24);

– Regulation (EU) 2018/1718 of the European Parliament and of the Council of 14 November 2018 amending Regulation (EC) No 726/2004 as regards the location of the seat of the European Medicines Agency (OJ L 291, 16.11.2018, p. 3);

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– Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance (OJ L 316, 14.11.2012, p. 38);

– Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1);

– Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11);

– Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009, p. 109);

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– Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121);

– Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

3. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

4. Regulation (EU) 2022/839 of the European Parliament and of the Council of 30 May 2022 laying down transitional rules for the packaging and labelling of veterinary medicinal products authorised or registered in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 (OJ L 148, 31.5.2022, p. 6).

5. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1), as amended by:

– Commission Regulation (EU) No 363/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 28);

– Commission Regulation (EU) No 362/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 26);

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– Commission Regulation (EU) No 914/2010 of 12 October 2010 (OJ L 269, 13.10.2010, p. 5);

– Commission Regulation (EU) No 890/2010 of 8 October 2010 (OJ L 266, 9.10.2010, p. 1);

– Commission Regulation (EU) No 761/2010 of 25 August 2010 (OJ L 224, 26.8.2010, p. 1);

– Commission Regulation (EU) No 759/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 39);

– Commission Regulation (EU) No 758/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 37).

6. Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: http://data.europa.eu/eli/reg/2024/568/oj).

PUBLIC

7. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7), as amended by:

   – Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 209, 4.8.2012, p. 4).

8. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1), as amended by:

   – Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (OJ L 153, 11.6.2019, p. 1).

9. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10).

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10. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121), as amended by:

    – Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241);

    – Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1).

11. Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10), as amended by:

    – Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 150, 9.6.2012, p. 68).

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12. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1), as amended by:

– Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 4, 7.1.2019, p. 24);

– Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (OJ L 152, 16.6.2009, p. 1);

– Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 (OJ L 378, 27.12.2006, p. 20).

13. Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6).

PUBLIC

14. Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

15. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

16. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44), as amended by:

    – Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).

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17. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28), as amended by:

– Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241);

– Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).

18. Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (OJ L 238, 16.9.2017, p. 44).

19. Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines (OJ L 135, 3.6.2003, p. 5), as amended by:

– Commission Regulation (EC) No 1876/2004 of 28 October 2004 (OJ L 326, 29.10.2004, p. 22);

– Commission Regulation (EC) No 1662/2005 of 11 October 2005 (OJ L 267, 12.10.2005, p. 19).

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20. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1), as amended by:

– Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union (OJ L 198, 25.7.2019, p. 241);

– Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14).

21. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

22. Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

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23. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34), as amended by:

– Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ L 378, 27.12.2006, p. 1);

– Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14).

24. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30) (only as regards the collection and testing of blood and blood components used as starting materials for manufacturing medicinal products), as amended by:

– Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14).

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25. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48) (only as regards the procurement, donation, coding and testing of tissue and cells, as well as the coding of donations and packaging thereof, used as starting materials for advanced therapy medicinal products as referred to in Regulation (EC) No 1394/2007 of the European Parliament and of the Council), as amended by:

– Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14).

PUBLIC

26. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj) (only as regards registration of substances of human origin (SoHO) from donors, history reviews of SoHO donors and medical examinations, testing of SoHO donors or of persons from whom SoHO are collected for autologous or within-relationship use, and collection, in the case of SoHO collected for the purposes of manufacturing medical devices, regulated by Regulation (EU) 2017/745, medicinal products, regulated by Directive 2001/83/EC, advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or investigational medicinal products, regulated by Regulation (EU) No 536/2014, and as regards storage, distribution, import and export, where carried out on SoHO up to and including their distribution to a manufacturer regulated by other Union legislation).

27. Commission Regulation (EU) 2017/880 of 23 May 2017 laying down rules on the use of a maximum residue limit established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (OJ L 135, 24.5.2017, p. 1).

PUBLIC

28. Commission Regulation (EU) 2018/782 of 29 May 2018 establishing the methodological principles for the risk assessment and risk management recommendations referred to in Regulation (EC) No 470/2009 (OJ L 132, 30.5.2018, p. 5), as amended by:

– Commission Regulation (EU) 2025/1101 of 3 June 2025 amending Regulation (EU) 2018/782 concerning the assessment by the European Medicines Agency of maximum residue limits for chemical-unlike biological substances (OJ L, 2025/1101, 4.6.2025, ELI: http://data.europa.eu/eli/reg/2025/1101/oj).

29. Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41), as amended by:

– Commission Regulation (EU) 2024/2858 of 12 November 2024 amending Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites in collagen (OJ L, 2024/2858, 13.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2858/oj);

– Commission Regulation (EU) 2023/411 of 23 February 2023 amending Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites (OJ L 59, 24.2.2023, p. 8).

PUBLIC

30. Commission Regulation (EC) No 540/95 of 10 March 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No 2309/93 (OJ L 55, 11.3.1995, p. 5).

31. Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No 2309/93 (OJ L 286, 8.11.1996, p. 6).

32. Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts “similar medicinal product” and “clinical superiority” (OJ L 103, 28.4.2000, p. 5), as amended by:

– Commission Regulation (EU) 2018/781 of 29 May 2018 amending Regulation (EC) No 847/2000 as regards the definition of the concept “similar medicinal product” (OJ L 132, 30.5.2018, p. 1).

PUBLIC

33. Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (OJ L 367, 22.12.2006, p. 33), as amended by:

– Commission Regulation (EU) No 122/2013 of 12 February 2013 amending Regulation (EC) No 1950/2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae (OJ L 42, 13.2.2013, p. 1).

34. Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1), as amended by:

– Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors (OJ L 330, 10.12.2013, p. 21);

– Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Two (OJ L 87, 31.3.2009, p. 109).

PUBLIC

35. Commission Decision 2008/911/EC of 21 November 2008 establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 328, 6.12.2008, p. 42), as amended by:

– Commission Decision 2010/180/EU of 25 March 2010 on amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 80, 26.3.2010, p. 52);

– Commission Decision 2010/30/EU of 9 December 2009 amending the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 12, 19.1.2010, p. 14);

– Commission Decision 2010/28/EC of 28 July 2009 amending the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products (OJ L 11, 16.1.2010, p. 12).

36. Regulation (EU) 2020/1043 of the European Parliament and of the Council of 15 July 2020 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19) (OJ L 231, 17.7.2020, p. 12).

PUBLIC

37. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33), as amended by:

– Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment, and amending Regulations (EC) No 166/2006 and (EU) No 995/2010 of the European Parliament and of the Council, Directives 2002/49/EC, 2004/35/EC, 2007/2/EC, 2009/147/EC and 2010/63/EU of the European Parliament and of the Council, Council Regulations (EC) No 338/97 and (EC) No 2173/2005, and Council Directive 86/278/EEC (OJ L 170, 25.6.2019, p. 115).

38. Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (OJ L 93, 9.4.2015, p. 56).

39. Commission Decision 2010/453/EU of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council (OJ L 213, 13.8.2010, p. 48).

PUBLIC

40. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1), as amended by:

– Regulation (EU) 2022/641 of the European Parliament and of the Council of 12 April 2022 amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (OJ L 118, 20.4.2022, p. 1).

II. COSMETIC PRODUCTS

ACTS REFERRED TO

1. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59), as amended by:

– Commission Regulation (EU) 2026/909 of 27 April 2026 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Benzyl Salicylate, Triphenyl Phosphate, Ammonium Silver Zinc Aluminium Silicate, Aluminium, water-soluble zinc salts, Acetylated Vetiver Oil, Citral, HC Blue No 18, HC Red No 18, HC Yellow No 16, Hydroxypropyl-p-phenylenediamine and its dihydrochloride salt, and DHHB in cosmetic products (OJ L, 2026/909, 28.4.2026, ELI: http://data.europa.eu/eli/reg/2026/909/oj);

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– Commission Regulation (EU) 2026/78 of 12 January 2026 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (OJ L, 2026/78, 13.1.2026, ELI: http://data.europa.eu/eli/reg/2026/78/oj);

– Commission Regulation (EU) 2025/877 of 12 May 2025 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (OJ L, 2025/877, 13.5.2025, ELI: http://data.europa.eu/eli/reg/2025/877/oj);

– Commission Regulation (EU) 2024/996 of 3 April 2024 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Vitamin A, Alpha-Arbutin and Arbutin and certain substances with potential endocrine disrupting properties in cosmetic products (OJ L, 2024/996, 4.4.2024, ELI: http://data.europa.eu/eli/reg/2024/996/oj);

– Commission Regulation (EU) 2024/858 of 14 March 2024 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of the nanomaterials Styrene/Acrylates copolymer, Sodium Styrene/Acrylates copolymer, Copper, Colloidal Copper, Hydroxyapatite, Gold, Colloidal Gold, Gold Thioethylamino Hyaluronic Acid, Acetyl heptapeptide-9 Colloidal gold, Platinum, Colloidal Platinum, Acetyl tetrapeptide-17 Colloidal Platinum and Colloidal Silver in cosmetics products (OJ L, 2024/858, 15.3.2024, ELI: http://data.europa.eu/eli/reg/2024/858/oj);

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– Commission Regulation (EU) 2023/1545 of 26 July 2023 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards labelling of fragrance allergens in cosmetic products (OJ L 188, 27.7.2023, p. 1);

– Commission Regulation (EU) 2023/1490 of 19 July 2023 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (OJ L 183, 20.7.2023, p. 7);

– Commission Regulation (EU) 2022/2195 of 10 November 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Butylated Hydroxytoluene, Acid Yellow 3, Homosalate and HAA299 in cosmetic products and correcting that Regulation as regards the use of Resorcinol in cosmetic products (OJ L 292, 11.11.2022, p. 32);

– Commission Regulation (EU) 2022/1531 of 15 September 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction and correcting that Regulation (OJ L 240, 16.9.2022, p. 3);

– Commission Regulation (EU) 2022/1181 of 8 July 2022 amending the preamble of Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 184, 11.7.2022, p. 3);

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– Commission Regulation (EU) 2022/1176 of 7 July 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products (OJ L 183, 8.7.2022, p. 51);

– Commission Regulation (EU) 2022/135 of 31 January 2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of Methyl-N-methylanthranilate in cosmetic products (OJ L 22, 1.2.2022, p. 2);

– Commission Regulation (EU) 2021/1902 of 29 October 2021 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction (OJ L 387, 3.11.2021, p. 120);

– Commission Regulation (EU) 2021/1099 of 5 July 2021 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 238, 6.7.2021, p. 29);

– Commission Regulation (EU) 2021/850 of 26 May 2021 amending and correcting Annex II and amending Annexes III, IV and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 188, 28.5.2021, p. 44);

– Commission Regulation (EU) 2020/1684 of 12 November 2020 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 379, 13.11.2020, p. 42);

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– Commission Regulation (EU) 2020/1683 of 12 November 2020 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 379, 13.11.2020, p. 34);

– Commission Regulation (EU) 2020/1682 of 12 November 2020 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 379, 13.11.2020, p. 31);

– Commission Regulation (EU) 2019/1966 of 27 November 2019 amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 307, 28.11.2019, p. 15);

– Commission Regulation (EU) 2019/1858 of 6 November 2019 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 286, 7.11.2019, p. 7);

– Commission Regulation (EU) 2019/1857 of 6 November 2019 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 286, 7.11.2019, p. 3);

– Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 137, 23.5.2019, p. 29);

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– Commission Regulation (EU) 2019/698 of 30 April 2019 amending Annexes III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 119, 7.5.2019, p. 66);

– Commission Regulation (EU) 2019/681 of 30 April 2019 amending Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 115, 2.5.2019, p. 5);

– Commission Regulation (EU) 2019/680 of 30 April 2019 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 115, 2.5.2019, p. 3);

– Commission Regulation (EU) 2018/1847 of 26 November 2018 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 300, 27.11.2018, p. 1);

– Commission Regulation (EU) 2018/978 of 9 July 2018 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 176, 12.7.2018, p. 3);

– Commission Regulation (EU) 2018/885 of 20 June 2018 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 158, 21.6.2018, p. 1);

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– Commission Regulation (EU) 2017/2228 of 4 December 2017 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 319, 5.12.2017, p. 2);

– Commission Regulation (EU) 2017/1413 of 3 August 2017 amending Annex IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 203, 4.8.2017, p. 1);

– Commission Regulation (EU) 2017/1410 of 2 August 2017 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 202, 3.8.2017, p. 1);

– Commission Regulation (EU) 2017/1224 of 6 July 2017 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 174, 7.7.2017, p. 16);

– Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

– Commission Regulation (EU) 2017/238 of 10 February 2017 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 36, 11.2.2017, p. 37);

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– Commission Regulation (EU) 2017/237 of 10 February 2017 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 36, 11.2.2017, p. 12);

– Commission Regulation (EU) 2016/1198 of 22 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 198, 23.7.2016, p. 10);

– Commission Regulation (EU) 2016/1143 of 13 July 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 189, 14.7.2016, p. 40);

– Commission Regulation (EU) 2016/1121 of 11 July 2016 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 187, 12.7.2016, p. 4);

– Commission Regulation (EU) 2016/1120 of 11 July 2016 amending Annex IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 187, 12.7.2016, p. 1);

– Commission Regulation (EU) 2016/622 of 21 April 2016 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 106, 22.4.2016, p. 7);

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– Commission Regulation (EU) 2016/621 of 21 April 2016 amending Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 106, 22.4.2016, p. 4);

– Commission Regulation (EU) 2016/314 of 4 March 2016 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 60, 5.3.2016, p. 59);

– Commission Regulation (EU) 2015/1298 of 28 July 2015 amending Annexes II and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 199, 29.7.2015, p. 22);

– Commission Regulation (EU) 2015/1190 of 20 July 2015 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 193, 21.7.2015, p. 115);

– Commission Regulation (EU) No 1004/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 282, 26.9.2014, p. 5);

– Commission Regulation (EU) No 1003/2014 of 18 September 2014 amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 282, 26.9.2014, p. 1);

– Commission Regulation (EU) No 866/2014 of 8 August 2014 amending Annexes III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and the Council on cosmetic products (OJ L 238, 9.8.2014, p. 3);

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– Commission Regulation (EU) No 358/2014 of 9 April 2014 amending Annexes II and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 107, 10.4.2014, p. 5);

– Commission Regulation (EU) No 1197/2013 of 25 November 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 315, 26.11.2013, p. 34);

– Commission Regulation (EU) No 658/2013 of 10 July 2013 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 190, 11.7.2013, p. 38);

– Commission Regulation (EU) No 483/2013 of 24 May 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 139, 25.5.2013, p. 8);

– Commission Regulation (EU) No 344/2013 of 4 April 2013 amending Annexes II, III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 114, 25.4.2013, p. 1).

2. First Commission Directive 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 383, 31.12.1980, p. 27), as amended by:

– Commission Directive 87/143/EEC of 10 February 1987 (OJ L 57, 27.2.1987, p. 56).

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3. Second Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 185, 30.6.1982, p. 1), as amended by:

   – Commission Directive 90/207/EEC of 4 April 1990 (OJ L 108, 28.4.1990, p. 92).

4. Commission Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products (OJ L 190, 11.7.2013, p. 31).

III. MEDICAL DEVICES

ACTS REFERRED TO

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

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4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (OJ L 131, 16.5.2002, p. 17), as amended by:

   – Commission Decision 2011/869/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 63);

   – Commission Decision 2009/886/EC of 27 November 2009 (OJ L 318, 4.12.2009, p. 25);

   – Commission Decision 2009/108/EC of 3 February 2009 (OJ L 39, 10.2.2009, p. 34).

5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

6. Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.8.2005, p. 41).

7. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45).

PUBLIC

8. Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (OJ L 212, 9.8.2012, p. 3).

9. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1), as amended by:

   – Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj);

   – Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: http://data.europa.eu/eli/reg/2024/568/oj);

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– Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (OJ L 80, 20.3.2023, p. 24);

– Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).

10. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176), as amended by:

– Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices (OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj);

– Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (OJ L 80, 20.3.2023, p. 24);

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– Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 19, 28.1.2022, p. 3).

11. Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj).

12. Commission Decision (EU) 2025/2371 of 26 November 2025 on the notice regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices referred to in Article 34(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council (OJ L, 2025/2371, 27.11.2025, ELI: http://data.europa.eu/eli/dec/2025/2371/oj).'

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