ISSN 1725-2423

Official Journal of the European Union

C 129

Volume 49

English edition

2 June 2006

Information and Notices

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([1]) Text with EEA relevance

I

(Information)

COMMISSION

Interest rate applied by the European Central Bank to its main refinancing operations [1]**:**

2,58 % on 1 June 2006

Euro exchange rates [2]

1 June 2006

(2006/C 129/01)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,2736	SIT	Slovenian tolar	239,64
JPY	Japanese yen	144,19	SKK	Slovak koruna	37,8
DKK	Danish krone	7,4582	TRY	Turkish lira	1,9915
GBP	Pound sterling	0,6847	AUD	Australian dollar	1,7081
SEK	Swedish krona	9,2655	CAD	Canadian dollar	1,4099
CHF	Swiss franc	1,5628	HKD	Hong Kong dollar	9,8803
ISK	Iceland króna	92,34	NZD	New Zealand dollar	2,0205
NOK	Norwegian krone	7,7835	SGD	Singapore dollar	2,02
BGN	Bulgarian lev	1,9558	KRW	South Korean won	1 206,42
CYP	Cyprus pound	0,575	ZAR	South African rand	8,6172
CZK	Czech koruna	28,254	CNY	Chinese yuan renminbi	10,2155
EEK	Estonian kroon	15,6466	HRK	Croatian kuna	7,256
HUF	Hungarian forint	263,2	IDR	Indonesian rupiah	11 895,42
LTL	Lithuanian litas	3,4528	MYR	Malaysian ringgit	4,6359
LVL	Latvian lats	0,696	PHP	Philippine peso	67,348
MTL	Maltese lira	0,4293	RUB	Russian rouble	34,505
PLN	Polish zloty	3,9383	THB	Thai baht	48,711
RON	Romanian leu	3,5293			

[1] Rate applied to the most recent operation carried out before the indicated day. In the case of a variable rate tender, the interest rate is the marginal rate.

[2] *Source:* reference exchange rate published by the ECB.

Commission communication in the framework of the implementation of 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

(2006/C 129/02)

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

ESO [1]	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 550:1994 Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization	—	
CEN	EN 552:1994 Sterilization of medical devices — Validation and routine control of sterilization by irradiation	—	
CEN	EN 554:1994 Sterilization of medical devices — Validation and routine control of sterilization by moist heat	—	
CEN	EN 556-1:2001 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices	EN 556:1994 + A1:1998	Date expired (30.4.2002)
CEN	EN 556-2:2003 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices	—	
CEN	EN 868-1:1997 Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods	—	
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 1041:1998 Information supplied by the manufacturer with medical devices	—	
CEN	EN 1174-1:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements	—	
CEN	EN 1174-2:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance	—	
CEN	EN 1174-3:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 3: Guide to the methods for validation of microbiological techniques	—	
CEN	EN ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 10993-4:2002 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002)	EN 30993-4:1993	Date expired (30.4.2003)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-9:1999 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	—	
CEN	EN ISO 10993-10:2002 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)	EN ISO 10993-10:1995	Date expired (31.3.2003)
CEN	EN ISO 10993-11:1995 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:1993)	—	
CEN	EN ISO 10993-12:2004 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2002)	EN ISO 10993-12:1996	Date expired (31.5.2005)
CEN	EN ISO 10993-13:1998 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	—	
CEN	EN ISO 10993-16:1997 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	—	
CEN	EN ISO 10993-17:2002 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	—	
CEN	EN ISO 10993-18:2005 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	—	
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2006
CEN	EN 13824:2004 Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements	—	
CEN	EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)	EN 540:1993	Date expired (31.8.2003)

ESO [1]	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)	—	
CEN	EN ISO 14971:2000 Medical devices — Application of risk management to medical devices (ISO 14971:2000)	EN 1441:1997	Date expired (31.3.2004)
	EN ISO 14971:2000/A1:2003	Note 3	Date expired (31.3.2004)
CEN	EN 30993-6:1994 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:1994)	—	
CEN	EN 45502-1:1997 Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer	—	
CEN	EN 45502-2-1:2004 Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)	—	

[1] ESO: European Standardisation Organisation:
— CEN: rue de Stassart 36, B-1050 Brussels, tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cenorm.be)
— CENELEC: rue de Stassart 35, B-1050 Brussels, tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (http://www.etsi.org)

Note 1 Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 3 In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to Directive 98/34/EC [1] of the European Parliament and of the Council amended by Directive 98/48/EC [2].

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

More information about harmonised standards on the Internet at:
http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/

[1] OJ L 204, 21.7.1998, p. 37.
[2] OJ L 217, 5.8.1998, p. 18.

Commission communication in the framework of the implementation of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

(2006/C 129/03)

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing	—	
CEN	EN 556-1:2001 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices	EN 556:1994 + A1:1998	Date expired (30.4.2002)
CEN	EN 591:2001 Instructions for use for in vitro diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for in vitro diagnostic instruments for self-testing	—	
CEN	EN 794-1:1997 Lung ventilators — Part 1: Particular requirements for critical care ventilators	—	
	EN 794-1:1997/A1:2000	Note 3	Date expired (31.5.2001)
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 1280-1:1997 Agent specific filling systems for anaesthetic vaporizers — Part 1: Rectangular keyed filling systems	—	
	EN 1280-1:1997/A1:2000	Note 3	Date expired (24.11.2000)
CEN	EN ISO 4135:2001 Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)	—	
CEN	EN 12286:1998 In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures	—	
	EN 12286:1998/A1:2000	Note 3	Date expired (24.11.2000)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 12287:1999 In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials	—	
CEN	EN 12322:1999 In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media	—	
	EN 12322:1999/A1:2001	Note 3	Date expired (30.4.2002)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)	EN ISO 13488:2000 EN ISO 13485:2000	31.7.2006
CEN	EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing	—	
CEN	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices	—	
CEN	EN 13640:2002 Stability testing of in vitro diagnostic reagents	—	
CEN	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents	—	
CEN	EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices — Statistical aspects	—	
CEN	EN 14254:2004 In vitro diagnostic medical devices — Single-use receptacles for the collection of specimens, other than blood, from humans	—	
CEN	EN 14820:2004 Single-use containers for human venous blood specimen collection	—	
CEN	EN ISO 14937:2000 Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000)	—	
CEN	EN ISO 14971:2000 Medical devices — Application of risk management to medical devices (ISO 14971:2000)	—	
	EN ISO 14971:2000/A1:2003	Note 3	Date expired (31.3.2004)
CEN	EN ISO 15197:2003 In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	—	
CEN	EN ISO 17511:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)	—	
CEN	EN ISO 18153:2003 In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)	—	

(1) ESO: European Standardisation Organisation:
— CEN: rue de Stassart 36, B-1050 Brussels, tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cenorm.be)
— CENELEC: rue de Stassart 35, B-1050 Brussels, tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (http://www.etsi.org)

Note 1 Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 3 In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to Directive 98/34/EC (1) of the European Parliament and Council amended by Directive 98/48/EC (2).

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

More information about harmonised standards on the Internet at
http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ L 217, 5.8.1998, p. 18.

Commission communication in the framework of the implementation of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

(2006/C 129/04)

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 285:1996 Sterilization — Steam sterilizers — Large sterilizers	—	
CEN	EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing	—	
CEN	EN 455-1:2000 Medical gloves for single use — Part 1: Requirements and testing for freedom from holes	EN 455-1:1993	Date expired (30.4.2001)
CEN	EN 455-2:2000 Medical gloves for single use — Part 2: Requirements and testing for physical properties (including Technical Corrigendum 1:1996)	EN 455-2:1995	Date expired (30.4.2001)
CEN	EN 455-3:1999 Medical gloves for single use — Part 3: Requirements and testing for biological evaluation	—	
CEN	EN 550:1994 Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization	—	
CEN	EN 552:1994 Sterilization of medical devices — Validation and routine control of sterilization by irradiation	—	
	EN 552:1994/A1:1999	Note 3	Date expired (30.11.1999)
	EN 552:1994/A2:2000	Note 3	Date expired (31.5.2001)
CEN	EN 554:1994 Sterilization of medical devices — Validation and routine control of sterilization by moist heat	—	
CEN	EN 556-1:2001 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices	EN 556:1994 + A1:1998	Date expired (30.4.2002)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 556-2:2003 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices	—	
CEN	EN 591:2001 Instructions for use for in vitro diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for in vitro diagnostic instruments for self-testing	—	
CEN	EN 737-1:1998 Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum	—	
CEN	EN 737-2:1998 Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems — Basic requirements	—	
	EN 737-2:1998/A1:1999	Note 3	Date expired (30.6.2000)
CEN	EN 737-3:1998 Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum	—	
	EN 737-3:1998/A1:1999	Note 3	Date expired (30.6.2000)
CEN	EN 737-4:1998 Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems	—	
CEN	EN 738-2:1998 Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators	—	
CEN	EN 738-3:1998 Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves	—	
	EN 738-3:1998/A1:2002	Note 3	Date expired (31.10.2002)
CEN	EN 738-4:1998 Pressure regulators for use with medical gases — Part 4: Low-pressure regulators intended for incorporation into medical equipment	—	
	EN 738-4:1998/A1:2002	Note 3	Date expired (31.10.2002)
CEN	EN 739:1998 Low-pressure hose assemblies for use with medical gases	—	
	EN 739:1998/A1:2002	Note 3	Date expired (31.10.2002)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 740:1998 Anaesthetic workstations and their modules — Particular requirements	—	
	EN 740:1998/A1:2004	Note 3	Date expired (31.7.2004)
	EN 740:1998/AC:1998		
CEN	EN 794-1:1997 Lung ventilators — Part 1: Particular requirements for critical care ventilators	—	
	EN 794-1:1997/A1:2000	Note 3	Date expired (31.5.2001)
CEN	EN 794-3:1998 Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators	—	
	EN 794-3:1998/A1:2005	Note 3	Date expired (31.12.2005)
CEN	EN 867-3:1997 Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test	—	
CEN	EN 868-1:1997 Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods	—	
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 1041:1998 Information supplied by the manufacturer with medical devices	—	
CEN	EN 1060-1:1995 Non-invasive sphygmomanometers — Part 1: General requirements	—	
	EN 1060-1:1995/A1:2002	Note 3	Date expired (30.11.2002)
CEN	EN 1060-2:1995 Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers	—	
CEN	EN 1060-3:1997 Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems	—	
	EN 1060-3:1997/A1:2005	Note 3	30.6.2006
CEN	EN 1060-4:2004 Non-invasive sphygmomanometers — Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 1089-3:2004 Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding	EN 1089-3:1997	Date expired (31.10.2004)
CEN	EN 1174-1:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements	—	
CEN	EN 1174-2:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance	—	
CEN	EN 1174-3:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 3: Guide to the methods for validation of microbiological techniques	—	
CEN	EN 1280-1:1997 Agent specific filling systems for anaesthetic vaporizers — Part 1: Rectangular keyed filling systems	—	
	EN 1280-1:1997/A1:2000	Note 3	Date expired (24.11.2000)
CEN	EN 1281-2:1995 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)	—	
CEN	EN 1282-2:2005 Tracheostomy tubes — Part 2: Paediatric tubes (ISO 5366-3:2001, modified)	EN 1282-2:1997	Date expired (31.12.2005)
CEN	EN 1422:1997 Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods	—	
CEN	EN 1618:1997 Catheters other than intravascular catheters — Test methods for common properties	—	
CEN	EN 1639:2004 Dentistry — Medical devices for dentistry — Instruments	EN 1639:1996	Date expired (31.12.2004)
CEN	EN 1640:2004 Dentistry — Medical devices for dentistry — Equipment	EN 1640:1996	Date expired (31.12.2004)
CEN	EN 1641:2004 Dentistry — Medical devices for dentistry — Materials	EN 1641:1996	Date expired (31.12.2004)
CEN	EN 1642:2004 Dentistry — Medical devices for dentistry — Dental implants	EN 1642:1996	Date expired (31.12.2004)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings	—	
CEN	EN 1782:1998 Tracheal tubes and connectors	—	
CEN	EN 1789:1999 Medical vehicles and their equipment — Road ambulances	—	
	EN 1789:1999/A1:2003	Note 3	Date expired (30.9.2003)
CEN	EN 1820:2005 Anaesthetic reservoir bags (ISO 5362:2000, modified)	EN 1820:1997	Date expired (31.12.2005)
CEN	EN 1865:1999 Specifications for stretchers and other patient handling equipment used in road ambulances	—	
CEN	EN 1970:2000 Adjustable beds for disabled persons — Requirements and test methods	—	
	EN 1970:2000/A1:2005	Note 3	Date expired (30.9.2005)
CEN	EN 1985:1998 Walking aids — General requirements and test methods	—	
CEN	EN ISO 4074:2002 Natural latex rubber condoms — Requirements and test methods (ISO 4074:2002)	EN 600:1996	Date expired (31.8.2005)
CEN	EN ISO 4135:2001 Anaesthetic and respiratory equipment — Vocabulary (ISO 4135:2001)	EN ISO 4135:1996	Date expired (28.2.2002)
CEN	EN ISO 5356-1:2004 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)	EN 1281-1:1997	Date expired (30.11.2004)
CEN	EN ISO 5366-1:2004 Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)	EN 1282-1:1996	Date expired (31.1.2005)
CEN	EN ISO 5840:2005 Cardiovascular implants — Cardiac valve prostheses (ISO 5840:2005)	EN 12006-1:1999	30.6.2006
CEN	EN ISO 7376:2003 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2003)	EN 1819:1997	Date expired (30.6.2004)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 7439:2002 Copper-bearing intra-uterine contraceptive devices — Requirements, tests (ISO 7439:2002)	—	
CEN	EN ISO 7886-3:2005 Sterile hypodermic syringes for single use — Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)	—	
CEN	EN ISO 8185:1997 Humidifiers for medical use — General requirements for humidification systems (ISO 8185:1997)	—	
CEN	EN ISO 8359:1996 Oxygen concentrators for medical use — Safety requirements (ISO 8359:1996)	—	
CEN	EN ISO 8835-4:2004 Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004) EN ISO 8835-4:2004/AC:2006	—	
CEN	EN ISO 8835-5:2004 Inhalational anaesthesia systems — Part 5: Anaesthesia ventilators (ISO 8835-5:2004) EN ISO 8835-5:2004/AC:2006	—	
CEN	EN ISO 9360-1:2000 Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)	—	
CEN	EN ISO 9360-2:2002 Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)	—	
CEN	EN ISO 9713:2004 Neurosurgical implants — Self-closing intracranial aneurysm clips (ISO 9713:2002)	—	
CEN	EN ISO 9919:2005 Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)	EN 865:1997	Date expired (30.9.2005)
CEN	EN ISO 10079-1:1999 Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)	EN ISO 10079-1:1996	Date expired (29.2.2000)
CEN	EN ISO 10079-2:1999 Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999)	EN ISO 10079-2:1996	Date expired (29.2.2000)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 10079-3:1999 Medical suction equipment — Part 3: Suction equipment powered from vacuum or pressure source (ISO 10079-3:1999)	EN ISO 10079-3:1996	Date expired (29.2.2000)
CEN	EN ISO 10524-1:2006 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)	EN 738-1:1997	31.8.2006
CEN	EN ISO 10535:1998 Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535:1998)	—	
CEN	EN ISO 10555-1:1996 Sterile, single-use intravascular catheters — Part 1: General requirements (ISO 10555-1:1995)	—	
	EN ISO 10555-1:1996/A1:1999	Note 3	Date expired (31.1.2000)
	EN ISO 10555-1:1996/A2:2004	Note 3	Date expired (30.11.2004)
CEN	EN ISO 10651-2:2004 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651-2:2004)	EN 794-2:1997	Date expired (31.1.2005)
CEN	EN ISO 10651-4:2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)	—	
CEN	EN ISO 10651-6:2004 Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)	—	
CEN	EN ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	
CEN	EN ISO 10993-3:2003 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2003)	EN 30993-3:1993	Date expired (30.4.2004)
CEN	EN ISO 10993-4:2002 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002)	EN 30993-4:1993	Date expired (30.4.2003)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-7:1995 Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:1995)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 10993-9:1999 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	—	
CEN	EN ISO 10993-10:2002 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)	EN ISO 10993-10:1995	Date expired (31.3.2003)
CEN	EN ISO 10993-11:1995 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:1993)	—	
CEN	EN ISO 10993-12:2004 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2002)	EN ISO 10993-12:1996	Date expired (31.5.2005)
CEN	EN ISO 10993-13:1998 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	—	
CEN	EN ISO 10993-14:2001 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	—	
CEN	EN ISO 10993-15:2000 Biological evaluation of medical devices — Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)	—	
CEN	EN ISO 10993-16:1997 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	—	
CEN	EN ISO 10993-17:2002 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	—	
CEN	EN ISO 10993-18:2005 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	EN 867-2:1997	Date expired (31.1.2006)
CEN	EN ISO 11197:2004 Medical supply units (ISO 11197:2004)	EN 793:1997	Date expired (30.6.2005)

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 11990:2003 Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts (ISO 11990:2003)	EN ISO 11990:1999	Date expired (31.10.2003)
CEN	EN 12006-2:1998 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 2: Vascular prostheses including cardiac valve conduits	—	
CEN	EN 12006-3:1998 Non active surgical implants — Particular requirements for cardiac and vascular implants — Part 3: Endovascular devices	—	
CEN	EN 12010:1998 Non-active surgical implants — Joint replacement implants — Particular requirements	—	
CEN	EN 12011:1998 Instrumentation to be used in association with non-active surgical implants — General requirements	—	
CEN	EN 12182:1999 Technical aids for disabled persons — General requirements and test methods	—	
CEN	EN 12183:1999 Manually propelled wheelchairs — Requirements and test methods	—	
CEN	EN 12184:1999 Electrically powered wheelchairs, scooters and their charges — Requirements and test methods	—	
CEN	EN 12218:1998 Rail systems for supporting medical equipment	—	
	EN 12218:1998/A1:2002	Note 3	Date expired (31.10.2002)
CEN	EN 12322:1999 In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media	—	
	EN 12322:1999/A1:2001	Note 3	Date expired (30.4.2002)
CEN	EN 12342:1998 Breathing tubes intended for use with anaesthetic apparatus and ventilators	—	
CEN	EN 12442-1:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 1: Analysis and management of risk	—	
CEN	EN 12442-2:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 2: Controls on sourcing, collection and handling	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 12442-3:2000 Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents	—	
CEN	EN 12470-1:2000 Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device	—	
CEN	EN 12470-2:2000 Clinical thermometers — Part 2: Phase change type (dot matrix) thermometers	—	
CEN	EN 12470-3:2000 Clinical thermometers — Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device	—	
CEN	EN 12470-4:2000 Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement	—	
CEN	EN 12470-5:2003 Clinical thermometers — Part 5: Performance of infra-red ear thermometers (with maximum device)	—	
CEN	EN 12523:1999 External limb prostheses and external orthoses — Requirements and test methods	—	
CEN	EN 12563:1998 Non-active surgical implants — Joint replacement implants — Specific requirements for hip joint replacement implants	—	
CEN	EN 12564:1998 Non-active surgical implants — Joint replacement implants — Specific requirements for knee joint replacement implants	—	
CEN	EN ISO 12870:2004 Ophthalmic optics — Spectacle frames — Requirements and test methods (ISO 12870:2004) EN ISO 12870:2004/AC:2005	EN ISO 12870:1997	Date expired (28.2.2005)
CEN	EN 13014:2000 Connections for gas sampling tubes to anaesthetic and respiratory equipment	—	
CEN	EN 13060:2004 Small steam sterilizers	—	
CEN	EN 13220:1998 Flow-metering devices for connection to terminal units of medical gas pipeline systems	—	
CEN	EN 13221:2000 High-pressure flexible connections for use with medical gases	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 13328-1:2001 Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance	—	
CEN	EN 13328-2:2002 Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects	—	
	EN 13328-2:2002/A1:2003	Note 3	Date expired (30.6.2004)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2006
CEN	EN 13503-8:2000 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements (ISO 11979-8:1999, modified)	—	
CEN	EN 13544-1:2001 Respiratory therapy equipment — Part 1: Nebulizing systems and their components	—	
	EN 13544-1:2001/A1:2004	Note 3	Date expired (31.12.2004)
CEN	EN 13544-2:2002 Respiratory therapy equipment — Part 2: Tubing and connectors	—	
CEN	EN 13544-3:2001 Respiratory therapy equipment — Part 3: Air entrainment devices	—	
CEN	EN 13624:2003 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area — Test method and requirements (phase 2, step 1)	—	
CEN	EN 13718-1:2002 Air, water and difficult terrain ambulances — Part 1: Medical device interface requirements for the continuity of patient care	—	
CEN	EN 13718-2:2002 Air, water and difficult terrain ambulances — Part 2: Operational and technical requirements for the continuity of patient care	—	
CEN	EN 13726-1:2002 Test methods for primary wound dressings — Part 1: Aspects of absorbency	—	
CEN	EN 13726-2:2002 Test methods for primary wound dressings — Part 2: Moisture vapour transmission rate of permeable film dressings	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 13727:2003 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area — Test method and requirements (phase 2, step 1)	—	
CEN	EN 13795-1:2002 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products	—	
CEN	EN 13795-2:2004 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — Part 2: Test methods	—	
CEN	EN 13824:2004 Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements	—	
CEN	EN 13826:2003 Peak expiratory flow meters	—	
CEN	EN 13867:2002 Concentrates for haemodialysis and related therapies	—	
CEN	EN 13976-1:2003 Rescue systems — Transportation of incubators — Part 1: Interface conditions	—	
CEN	EN 13976-2:2003 Rescue systems — Transportation of incubators — Part 2: System requirements	—	
CEN	EN 14079:2003 Non-active medical devices — Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze	—	
CEN	EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)	EN 540:1993	Date expired (31.8.2003)
CEN	EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)	—	
CEN	EN ISO 14160:1998 Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants (ISO 14160:1998)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 14180:2003 Sterilizers for medical purposes — Low temperature steam and formaldehyde sterilizers — Requirements and testing	—	
CEN	EN 14299:2004 Non active surgical implants — Particular requirements for cardiac and vascular implants — Specific requirements for arterial stents	—	
CEN	EN 14348:2005 Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants — Test methods and requirements (phase 2, step 1)	—	
CEN	EN ISO 14408:2005 Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information (ISO 14408:2005)	—	
CEN	EN ISO 14534:2002 Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements (ISO 14534:2002)	EN ISO 14534:1997	Date expired (31.12.2002)
CEN	EN ISO 14602:1998 Non-active surgical implants — Implants for Osteosynthesis — Particular requirements (ISO 14602:1998)	—	
CEN	EN ISO 14630:2005 Non-active surgical implants — General requirements (ISO 14630:2005)	EN ISO 14630:1997	Date expired (30.11.2005)
CEN	EN 14683:2005 Surgical masks — Requirements and test methods	—	
CEN	EN ISO 14889:2003 Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses (ISO 14889:2003)	EN ISO 14889:1997	Date expired (30.11.2003)
CEN	EN ISO 14937:2000 Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000)	—	
CEN	EN ISO 14971:2000 Medical devices — Application of risk management to medical devices (ISO 14971:2000)	EN 1441:1997	Date expired (31.3.2004)
	EN ISO 14971:2000/A1:2003	Note 3	Date expired (31.3.2004)
CEN	EN ISO 15001:2004 Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003)	—	
CEN	EN ISO 15004:1997 Ophthalmic instruments — Fundamental requirements and test methods (ISO 15004:1997)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	—	
	EN ISO 15225:2000/A1:2004	Note 3	Date expired (31.8.2004)
CEN	EN ISO 15747:2005 Plastics containers for intravenous injection (ISO 15747:2003)	—	
CEN	EN ISO 17510-1:2002 Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy devices (ISO 17510-1:2002)	—	
CEN	EN ISO 17510-2:2003 Sleep apnoea breathing therapy — Part 2: Masks and application accessories (ISO 17510-2:2003)	—	
CEN	EN ISO 17664:2004 Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)	—	
CEN	EN ISO 18777:2005 Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)	—	
CEN	EN ISO 18778:2005 Respiratory equipment — Infant monitors — Particular requirements (ISO 18778:2005)	—	
CEN	EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures — Particular requirements (ISO 18779:2005)	—	
CEN	EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)	—	
	EN 20594-1:1993/A1:1997	Note 3	Date expired (31.5.1998)
CEN	EN ISO 21647:2004 Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004)	EN 12598:1999 EN 864:1996 EN ISO 11196:1997	Date expired (31.5.2005)
	EN ISO 21647:2004/AC:2006		
CEN	EN ISO 22612:2005 Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985)	—	
	EN 27740:1992/A1:1997	Note 3	Date expired (31.5.1998)
CEN	EN 30993-6:1994 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:1994)	—	
CEN	EN 46003:1999 Quality systems — Medical devices — Particular requirements for the application of EN ISO 9003	—	

(1) ESO: European Standardisation Organisation:
— CEN: rue de Stassart 36, B-1050 Brussels, tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cenorm.be)
— CENELEC: rue de Stassart 35, B-1050 Brussels, tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (http://www.etsi.org)

Note 1 Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 3 In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to Directive 98/34/EC (1) of the European Parliament and of the Council amended by Directive 98/48/EC (2).

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

More information about harmonised standards on the Internet at
http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ L 217, 5.8.1998, p. 18.

Notice regarding the scope of the partial interim review on imports of Polyethylene Terephthalate ('PET') originating in, *inter alia*, the Republic of Korea

(2006/C 129/05)

On 1 December 2005, the Commission published in the *Official Journal of the European Union* a Notice of Initiation of an expiry review on the anti-dumping measures in force against imports of Polyethylene Terephthalate ('PET') originating in India, Indonesia, the Republic of Korea, Malaysia, Taiwan and Thailand and a partial interim review on the same measures against imports originating in Taiwan and the Republic of Korea [1].

This scope of the present Notice is limited to the partial interim review and concerns only the Republic of Korea.

Clarification regarding the scope of the partial interim review

In point 4.2 of the Notice of Initiation, the following three companies are mentioned as being subject to the partial interim review: Daehan Synthetic Fibre Co. Ltd, SK Chemicals Co. Ltd and KP Chemicals Corp.

In the light of information gathered as part of the questionnaire response to the Notice of Initiation, it has come to the attention of the Commission that companies *related to* the three abovementioned companies also produce and/or distribute PET.

In order to avoid any misunderstanding about the exact scope of the investigation, it is hereby clarified that all companies related to [2] Daehan Synthetic Fibre Co. Ltd, SK Chemicals Co. Ltd and KP Chemicals Corp are also part of the scope of this investigation. If anti-dumping duties are called for by the outcome of this investigation, they will be calculated on the basis of the information obtained from the group of all related companies involved in the production and distribution of PET and will be set accordingly.

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[1] OL C 304, 1.12.2005, p. 9.

[2] For the notion of relationship reference is made to Article 143(1) of Commission Regulation (EEC) No 2454/93 of 2 July 1993 (give full reference).