

# Official Journal

## of the European Union

C 54

Volume 51

English edition

### Information and Notices

27 February 2008

<u>Notice No</u>	Contents	Page
	II <i>Information</i>	
	INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES	
	<b>Commission</b>	
2008/C 54/01	Authorisation for State aid pursuant to Articles 87 and 88 of the EC Treaty — Cases where the Commission raises no objections <sup>(1)</sup> .....	1
	III <i>Preparatory Acts</i>	
	COUNCIL	
2008/C 54/02	Initiative of the Kingdom of Belgium, the Czech Republic, the Republic of Estonia, the Kingdom of Spain, the French Republic, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic and the Kingdom of Sweden with a view to adopting a Council Decision of ... on the strengthening of Eurojust and amending Decision 2002/187/JHA .....	4
2008/C 54/03	Initiative of the Republic of Slovenia, the French Republic, the Czech Republic, the Kingdom of Sweden, the Kingdom of Spain, the Kingdom of Belgium, the Republic of Poland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Slovak Republic, the Republic of Estonia, the Republic of Austria and the Portuguese Republic, with a view to adopting a Council Decision of ... on the European Judicial Network .....	14



IV *Notices*

## NOTICES FROM EUROPEAN UNION INSTITUTIONS AND BODIES

**Commission**

2008/C 54/04	Euro exchange rates .....	18
--------------	---------------------------	----

## NOTICES FROM MEMBER STATES

2008/C 54/05	Information communicated by Member States regarding State aid granted under Commission Regulation (EC) No 68/2001 on the application of Articles 87 and 88 of the EC Treaty to training aid <sup>(1)</sup> .....	19
2008/C 54/06	Commission communication in the framework of the implementation of the 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 <sup>(1)</sup> .....	22
2008/C 54/07	Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices <sup>(1)</sup> .....	26
2008/C 54/08	Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices <sup>(1)</sup> .....	29

V *Announcements*

## PROCEDURES RELATING TO THE IMPLEMENTATION OF THE COMPETITION POLICY

**Commission**

2008/C 54/09	Prior notification of a concentration (Case COMP/M.5073 — Scholz/TTC/GMPL JV) — Candidate case for simplified procedure <sup>(1)</sup> .....	43
--------------	--	----



<sup>(1)</sup> Text with EEA relevance

## II

(Information)

## INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES

## COMMISSION

**Authorisation for State aid pursuant to Articles 87 and 88 of the EC Treaty****Cases where the Commission raises no objections**

(Text with EEA relevance)

(2008/C 54/01)

Date of adoption of the decision	20.7.2005
Reference number of the aid	N 370/04
Member State	France
Region	—
Title (and/or name of the beneficiary)	Aide à la restructuration de l'Imprimerie Nationale
Legal basis	—
Type of measure	Individual aid
Objective	Restructuring of firms in difficulty
Form of aid	Direct grant, Transactions not on market terms
Budget	Overall budget: EUR 197 million
Intensity	—
Duration	2004-2008
Economic sectors	Manufacturing industry
Name and address of the granting authority	Agence des participations de l'État 139, rue de Bercy F-75572 Paris Cedex 12
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

[http://ec.europa.eu/community\\_law/state\\_aids/](http://ec.europa.eu/community_law/state_aids/)

Date of adoption of the decision	15.1.2008
Reference number of the aid	N 393/07
Member State	Netherlands
Region	Deventer, Provincie Overijssel
Title (and/or name of the beneficiary)	Subsidie aan NV Bergkwartier
Legal basis	Enkelvoudig Programmeringsdocument voor de structurele bijstandsverlening van de Gemeenschap in de onder doelstelling 2 vallende regio Oost-Nederland
Type of measure	Individual aid
Objective	Heritage conservation, Regional development, Employment
Form of aid	Direct grant
Budget	Overall budget: EUR 0,89 million
Intensity	—
Duration	9.11.2006-15.8.2008
Economic sectors	Real Estate
Name and address of the granting authority	Gemeente Deventer Provincie Overijssel
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

[http://ec.europa.eu/community\\_law/state\\_aids/](http://ec.europa.eu/community_law/state_aids/)

Date of adoption of the decision	12.12.2007
Reference number of the aid	N 436/07
Member State	Spain
Region	Castilla y León
Title (and/or name of the beneficiary)	Prórroga y modificación de ayuda para acciones de ahorro, eficiencia energética, cogeneración y energías renovables, Castilla y León
Legal basis	Orden EYE 2002/2006, de 18 de diciembre; Orden EYE 1311/2005, de 3 de octubre
Type of measure	Aid scheme
Objective	Environmental protection
Form of aid	Direct grant
Budget	Overall budget: EUR 2 million
Intensity	45 %

Duration	1.1.2007-15.10.2007
Economic sectors	All sectors
Name and address of the granting authority	Consejería de Economía y Empleo, D.G. Energia y Minas Avda Reyes Leoneses, 11 E-24008 Leon
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

[http://ec.europa.eu/community\\_law/state\\_aids/](http://ec.europa.eu/community_law/state_aids/)

Date of adoption of the decision	11.12.2007
Reference number of the aid	N 515/07
Member State	Sweden
Region	—
Title (and/or name of the beneficiary)	Stöd till Posten AB — förlängning 2008
Legal basis	Lag (2001:1276) om grundläggande kassaservice; förordning (2005:882) om grundläggande kassaservice
Type of measure	Individual aid
Objective	Services of general economic interest
Form of aid	Direct grant
Budget	Annual budget: SEK 200 million Overall budget: SEK 200 million
Intensity	—
Duration	1.1.2008-31.12.2008
Economic sectors	Post and telecommunications, Financial intermediation
Name and address of the granting authority	Näringsdepartementet Jakobsgatan 26 S-10 333 Stockholm
Other information	—

The authentic text(s) of the decision, from which all confidential information has been removed, can be found at:

[http://ec.europa.eu/community\\_law/state\\_aids/](http://ec.europa.eu/community_law/state_aids/)

## III

(Preparatory Acts)

## COUNCIL

**Initiative of the Kingdom of Belgium, the Czech Republic, the Republic of Estonia, the Kingdom of Spain, the French Republic, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic and the Kingdom of Sweden with a view to adopting a Council Decision of ... on the strengthening of Eurojust and amending Decision 2002/187/JHA**

(2008/C 54/02)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 31 and 34(2)(c) thereof,

Having regard to the initiative of the Kingdom of Belgium, the Czech Republic, the Republic of Estonia, the Kingdom of Spain, the French Republic, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Republic of Austria, the Republic of Poland, the Portuguese Republic, the Republic of Slovenia, the Slovak Republic and the Kingdom of Sweden with a view to adopting a Council Decision concerning the strengthening of Eurojust and amending Decision 2002/187/JHA,

Having regard to the Opinion of the European Parliament,

Whereas:

- (1) Eurojust was set up by Decision 2002/187/JHA <sup>(1)</sup> as a body of the EU with legal personality to stimulate and improve coordination and cooperation between competent judicial authorities of the Member States.
- (2) After more than 5 years, it is now time to assess the experience gained by Eurojust and further to enhance its operational effectiveness by taking account of that experience.
- (3) The time has come to ensure that Eurojust becomes more operational and that the status of national members are approximated.

<sup>(1)</sup> OJ L 63, 6.3.2002, p. 1. Decision as amended by Decision 2003/659/JHA (OJ L 245, 29.9.2003, p. 44).

- (4) The setting up of an Emergency Coordination Cell within Eurojust is necessary to make Eurojust available around the clock and enable it to intervene in urgent cases.

- (5) Eurojust national coordination systems should be set up in the Member States to coordinate the work carried out by the national correspondents for Eurojust, the national correspondent for terrorism matters, the national correspondent for the European Judicial Network, other contact points of the European Judicial Network and representatives in the Network for Joint Investigation Teams and of the Networks set up by Council Decision 2002/494/JHA <sup>(2)</sup> (war crime networks), Council Decision 2007/845/JHA <sup>(3)</sup> (asset recovery offices) and by any forthcoming decision on a contact point network against corruption.

- (6) The issue of duplication of efforts and clarification of the division of work between Eurojust and the European Judicial Network needs to be resolved, while maintaining the specificity of the European Judicial Network. While maintaining its specificity as a network and its national and operational capacities, the European Judicial Network should be able to draw on the Community budget for operational expenses.

- (7) It is also necessary to strengthen Eurojust's capacity to work with external partners, such as third countries, Europol, OLAF and Frontex.

<sup>(2)</sup> Council Decision of 13 June 2002 setting up a European network of contact points in respect of persons responsible for genocide, crimes against humanity and war crimes (OJ L 167, 26.6.2002, p. 1).

<sup>(3)</sup> Council Decision of 6 December 2007 concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds from, or other property related to, crime (OJ L 332, 18.12.2007, p. 103).

(8) Provision should be made for Eurojust to second liaison magistrates to third countries,

2. The ECC shall be composed of one representative per Member State, who may be either the national member, his or her deputy, or an assistant entitled to replace the national member. The ECC shall be contactable and able to act on an around the clock basis.

HAS DECIDED AS FOLLOWS:

#### Article 1

Decision 2002/187/JHA is hereby amended as follows:

1. in Article 2:

(a) paragraph 2 shall be replaced by the following:

'2. Each national member shall be assisted by one deputy and by another person as an assistant member. The national member or, in his absence, his deputy shall be required to have their permanent place of work at the seat of Eurojust. If necessary and with the agreement of the College referred to in Article 10, several persons may assist the national member, either as assistants or as seconded national experts under Article 30.;

(b) the following paragraphs shall be added:

'3. The deputy shall replace the national member in case of absence. An assistant may also replace the national member. To replace the national member, the deputy and the assistant shall fulfil the criteria provided for in paragraph 1.

4. Eurojust shall also be linked to a Eurojust national coordination system in accordance with Article 12. Operational expenses of this system may be covered by Eurojust's budget in accordance with Article 33.

5. Eurojust shall have the possibility of seconding liaison magistrates to third countries in accordance with the provisions of this Decision.;

2. Article 4(1) shall be replaced by the following:

'1. The general competence of Eurojust shall cover:

(a) the types of crime and the offences in respect of which Europol is at all times competent to act pursuant to Article 2 of the Europol Convention of 26 July 1995 and the Annex thereto;

(b) other offences committed together with the types of crime and the offences referred to in point (a).;

3. the following Article shall be inserted:

'Article 5a

#### Emergency Coordination Cell (ECC)

1. In order to fulfil its tasks on an emergency basis, Eurojust shall set up an "Emergency Coordination Cell" (ECC).

3. When in urgent cases a request for judicial cooperation needs to be executed in several Member States, the competent authority may forward it to the ECC through the representative of its Member State in the ECC. The representative of the Member State concerned in the ECC shall transmit the request to the competent authorities of the relevant Member States for execution. Where no competent national authority has been identified or it is not possible to identify it in a timely manner, the member of the ECC shall have the power to execute the request himself.

4. The representative referred to in paragraph 2 may use the powers conferred on him under Article 9a with a view to following up decisions taken in the ECC including, where applicable, the power to execute the request referred to in paragraph 3.

5. Eurojust shall take the necessary measures to ensure that national authorities can easily and at any time contact the ECC directly.;

4. Article 6 shall be replaced by the following:

'Article 6

#### Tasks of Eurojust acting through its national members

1. When Eurojust acts through its national members concerned, it:

(a) may ask the competent authorities of the Member States concerned, giving its reasons, to:

(i) undertake an investigation or prosecution of specific acts;

(ii) accept that one of them may be in a better position to undertake an investigation or to prosecute specific acts;

(iii) coordinate between the competent authorities of the Member States concerned;

(iv) set up a joint investigation team in keeping with the relevant cooperation instruments;

- (v) provide it with any information that is necessary for it to carry out its tasks;
  - (vi) take special investigative measures;
  - (vii) take any other measure justified for the investigation or prosecution;
- (b) shall ensure that the competent authorities of the Member States concerned inform each other on investigations and prosecutions of which it has been informed;
- (c) shall assist the competent authorities of the Member States, at their request, in ensuring the best possible coordination of investigations and prosecutions;
- (d) shall give assistance in order to improve cooperation between the competent national authorities;
- (e) shall cooperate and consult with the European Judicial Network, including making use of and contributing to the improvement of its documentary database;
- (f) shall, in the cases referred to in Article 3(2) and (3) and with the agreement of the College, assist investigations and prosecutions concerning the competent authorities of only one Member State;
- (g) may, in case of partial or inadequate execution of a request for judicial assistance, ask the competent judicial authority for supplementary investigation in order for the request to be fully executed.
2. The Member States shall also ensure that competent national authorities answer without delay requests made under this Article.;
5. Article 7 shall be replaced by the following:

*'Article 7*

**Tasks of Eurojust acting as a College**

1. When Eurojust acts as a College, it:
- (a) may in relation to the types of crime and the offences referred to in Article 4(1) ask the competent authorities of the Member States concerned, giving its reasons:
    - (i) to undertake an investigation or prosecution of specific acts;
    - (ii) to accept that one of them may be in a better position to undertake an investigation or to prosecute specific acts;

- (iii) to coordinate between the competent authorities of the Member States concerned;
  - (iv) to set up a joint investigation team in keeping with the relevant cooperation instruments;
  - (v) to provide it with any information that is necessary for it to carry out its tasks;
- (b) shall ensure that the competent authorities of the Member States inform each other of investigations and prosecutions of which it has been informed and which have repercussions at Union level or which might affect Member States other than those directly concerned;
- (c) shall assist the competent authorities of the Member States, at their request, in ensuring the best possible coordination of investigations and prosecutions;
- (d) shall give assistance in order to improve cooperation between the competent authorities of the Member States, in particular on the basis of Europol's analysis;
- (e) shall cooperate and consult with the European Judicial Network, including making use of and contributing to the improvement of its documentary database;
- (f) may assist Europol, in particular by providing it with opinions based on analyses carried out by Europol;
- (g) may supply logistical support in the cases referred to in points (a), (c) and (d). Such logistical support may include assistance for translation, interpretation and the organisation of coordination meetings.

2. Where two or more national members are not in agreement on how to resolve a case of conflicts of jurisdiction as regards the undertaking of investigations or prosecution pursuant to Article 6, the College shall issue a written non-binding opinion on how the case should be solved. The opinion of the College shall be promptly forwarded to the Member States concerned.

3. Notwithstanding the provisions contained in any instruments adopted under Title VI of the Treaty, the requesting competent authorities may report to Eurojust any refusal or difficulty concerning the execution of a request for judicial cooperation and request the College to issue a written non-binding opinion on how the case should be solved. The opinion of the College shall be promptly forwarded to the Member States concerned.



4. The College may, on a request from the competent national authorities concerned and in cooperation with them, decide that the relevant expenditure of a joint investigation team set up under Article 13 of the Convention of 29 May 2000 on Mutual Assistance in Criminal Matters between the Member States of the European Union or Framework Decision 2002/465/JHA (\*) shall be regarded as operational expenditure of Eurojust within the meaning of Article 41(3) of the Treaty.

(\*) OJ L 162, 20.6.2002, p. 1.;

6. Article 8 shall be replaced by:

*'Article 8*

### **Effects of decisions of Eurojust**

If the competent authorities of the Member States concerned decide not to comply with a request referred to in Articles 6(1)(a), 6(1)(g), 7(1)(a), 7(2) and 7(3), they shall inform Eurojust of their decision and of the reasons for it.;

7. in Article 9:

(a) paragraphs 1 and 2 shall be replaced by:

'1. National members shall be subject to the national law of their Member State as regards their status. The length of a national member's term of office shall be at least 4 years. The Member States of origin may renew the term of office. The national member shall not be removed before the end of a term without prior information to the Council and indication of the reason therefor. Where a national member is President or Vice-President of Eurojust, his term of office as a member shall at least be such that he can fulfil his function as President or Vice-President for the full elected term.

2. All information exchanged between Eurojust and Member States, including requests made within the framework of Article 6(1)(a) and 6(1)(g), shall be directed through the national member.;

(b) paragraph 3 shall be deleted;

(c) paragraph 4 shall be replaced by the following:

'4. In order to meet Eurojust's objectives, the national member shall have full access to:

(a) the information contained in the following registers:

- (i) national criminal records;
- (ii) registers of arrested persons;
- (iii) investigation registers;

(iv) DNA registers;

(b) registers, other than those in (a), of his Member State containing information that is necessary for him to be able to fulfil his tasks.;

(d) the following paragraph shall be inserted:

'4a. The modalities of access referred to in paragraph 4 shall at least be the same as those stipulated by national law in the case of a prosecutor, judge or police officer of equivalent competence.;

(e) paragraph 6 shall be deleted;

8. the following Article shall be inserted:

*'Article 9a*

### **Powers of the national member conferred upon him at national level**

1. Each Member State shall define the nature and extent of the judicial powers it grants its national member as regards judicial cooperation in respect of that State. They shall include at least the following equivalent powers:

(a) receiving, transmitting, preparing the execution of, providing supplementary information in relation to, and monitoring the execution of, requests for judicial cooperation regarding instruments adopted under Title VI of the Treaty, including instruments giving effect to the principle of mutual recognition;

(b) preparing the setting up of, and participating in, joint investigation teams set up under Article 13 of the Convention of 29 May 2000 on Mutual Assistance in Criminal Matters between the Member States of the European Union or Framework Decision 2002/465/JHA, as regards its own Member State, including all joint investigation teams supported by Eurojust in accordance with Article 7(4) of this Decision;

(c) performing all the tasks of competent national authorities in relation to the Analysis Work Files of Europol.

2. National members may, in their capacity as national judicial authorities, in agreement with a competent national authority or at its request and on a case-by-case basis, exercise the following delegated powers:

(a) issuing and completing requests for judicial cooperation regarding instruments adopted under Title VI of the Treaty, including instruments giving effect to the principle of mutual recognition;

- (b) ordering search and seizure measures;
- (c) authorising and coordinating controlled deliveries.

3. National members may, in urgent cases and where no competent national authority has been identified or it is not possible to identify it in a timely manner, be able to authorise and coordinate controlled deliveries.

4. The powers exercised under paragraph 1(a) shall in the first instance always be exercised by a competent national authority.

5. When the powers referred to in paragraph 1 and 3 have been exercised by a national member, the competent authority shall be informed promptly.

6. When constitutional rules regarding the division of powers between prosecutors and judges make it impossible to confer one or more of the powers referred to in paragraphs 1, 2 and 3 of this Article and in Article 5a(3) upon the national member, he shall at least be competent to issue a request to the authority competent for the carrying out of such powers.

7. Each Member State shall also define the right for a national member to act in relation to foreign judicial authorities, in accordance with its international commitments.

8. When appointing its national member and at any other time if appropriate, the Member State shall notify Eurojust and the Council General Secretariat of its decision regarding the implementation of paragraphs 1 to 3 so that the latter can inform the other Member States. The Member States shall undertake to accept and recognise the prerogatives thus conferred insofar as they are in conformity with international commitments.

9. In the performance of his tasks, a national member shall, where appropriate, make it known whether he is acting in accordance with the judicial powers granted to him under this Article.;

9. Article 10(2) shall be replaced by the following:

‘2. After consulting the Joint Supervisory Board provided for in Article 23 as regards the provisions on the processing of personal data, the Council shall approve Eurojust’s rules of procedure on a proposal from the College which has previously been adopted by a two-thirds majority by the latter. The provisions of the rules of procedure which concern the processing of personal data may be made the subject of separate approval by the Council.’;

10. Article 12 shall be replaced by the following:

‘Article 12

### **Eurojust national coordination system**

1. Each Member State shall designate one or more national correspondents for Eurojust.
2. Each Member State shall set up a Eurojust national coordination system to ensure coordination of the work carried out by:
  - (a) the national correspondents for Eurojust;
  - (b) the national correspondent for terrorism matters;
  - (c) the national correspondent for the European Judicial Network and up to three other contact points of the European Judicial Network;
  - (d) national members or contact points of the Network for Joint Investigation Teams and of the Networks set up by Council Decision 2002/494/JHA (\*) (war crime networks), Council Decision 2007/845/JHA (\*\*) (asset recovery offices) and by any forthcoming decision on a contact point network against corruption.
3. The persons referred to in paragraphs 1 and 2 shall maintain their position and status under national law.
4. One of the national correspondents for Eurojust shall be responsible for the functioning of the Eurojust national coordination system.
5. The Eurojust national coordination system shall:
  - (a) be connected to the Case Management System of Eurojust;
  - (b) assist Eurojust in determining whether a case should be dealt with by Eurojust or the European Judicial Network;
  - (c) facilitate, within the Member State, the carrying out of the tasks of Eurojust, in particular by allowing the national member to identify proper authorities for the execution of requests for judicial cooperation;
  - (d) maintain close relations with the Europol National Unit and in particular:
    - (i) be informed and consulted on the participation of the Member State concerned in an Analysis Work File and be informed of the functioning and results of such Analysis Work Files;
    - (ii) be informed of any request of Europol to undertake an investigation or to set up a joint investigation team and to inform the Europol National Unit of such requests made by Eurojust.

6. The relations between the national member and national correspondents shall not preclude direct relations between the national member and his competent authorities.

7. Nothing in this Article shall be understood as affecting direct contacts between competent judicial authorities as provided for in instruments on judicial cooperation, such as Article 6 of the Convention of 29 May 2000 on Mutual Assistance in Criminal Matters between the Member States of the European Union.

8. Expenses of the Eurojust national coordination system such as rent, equipment, telecommunications and salaries of administrative staff may be considered operational expenses of Eurojust in accordance with Article 30.

(\*) Council Decision of 13 June 2002 setting up a European network of contact points in respect of persons responsible for genocide, crimes against humanity and war crimes (OJ L 167, 26.6.2002, p. 1).

(\*\*) Council Decision of 6 December 2007 concerning cooperation between Asset Recovery Offices of the Member States in the field of tracing and identification of proceeds from, or other property related to, crime (OJ L 332, 18.12.2007, p. 103).<sup>1</sup>

11. in Article 13:

(a) in paragraph 2:

- (i) the words 'In accordance with Article 9,' shall be deleted;
- (ii) the following sentence shall be added at the end of the paragraph: 'In particular national members who have not been informed of a case which concerns them shall be promptly informed.';

(b) the following paragraphs shall be added:

'3. This Article shall be without prejudice to other obligations regarding the transmission of information to Eurojust, including Council Decision 2005/671/JHA of 20 September 2005 on the exchange of information on a cooperation concerning terrorist offences (\*).

4. Member States shall ensure that national members are informed of the preparation of the setting up of a joint investigation team, whether it is set up under Article 13 of the Convention of 29 May 2000 on Mutual Assistance in Criminal Matters between the Member States of the European Union or Framework Decision 2002/465/JHA, and of subsequent developments related to such teams.

5. Member States shall ensure that their national member is informed in a timely manner, at an early stage, and as soon as the information is available of all criminal investigations concerning three or more States, two or more of which are Member States, that fall within the remit of Eurojust and insofar as necessary for the performance of Eurojust's functions, in particular where parallel letters rogatory are needed in several States or where there is a need for coordination by Eurojust or in cases of positive or negative conflicts of jurisdiction. The Member States shall ensure that the obligation to report is supervised at national level.

6. As a first step, Member States shall implement paragraph 5 with regard to cases relating to the following offences:

- (a) trafficking in drugs;
- (b) trafficking in human beings and arms;
- (c) trafficking in nuclear waste;
- (d) trafficking in works of art;
- (e) trading in endangered species;
- (f) trading in human organs;
- (g) money laundering;
- (h) fraud, including fraud against the Community's financial interests;
- (i) counterfeiting, including of the euro;
- (j) terrorism, including financing of terrorism;
- (k) environmental crime;
- (l) other forms of organised crime.

7. Member States shall apply paragraph 5 to offences other than those referred to in paragraph 6 within three years from the date referred to in Article 2.

8. Member States shall ensure that their national member is also informed of:

- (a) all requests for judicial cooperation regarding instruments adopted under Title VI of the Treaty, including instruments giving effect to the principle of mutual recognition, sent by their competent authorities in cases involving at least three States, two or more of which are Member States;

- (b) all controlled deliveries and undercover investigations affecting at least three States, at least two of which are Member States;
- (c) all refusals of requests for judicial cooperation regarding instruments adopted under Title VI of the Treaty, including instruments giving effect to the principle of mutual recognition;
- (d) all requests for mutual legal assistance emanating from a non-Member State where it appears that these requests are part of an investigation involving other requests sent by that non-Member State to, at least, two other Member States.

9. In addition, competent authorities shall provide the latter with any other information which the latter deems necessary to fulfil its tasks.

10. Information referred to in this Article shall be transmitted to Eurojust in a structured way.

(\*) OJ L 253, 29.9.2005, p. 22.;

12. the following Article shall be inserted:

*'Article 13a*

**Information provided by Eurojust to national authorities**

1. On its own initiative Eurojust shall provide national competent authorities with information and feedback on the results of the processing of information, including the existence of links with cases already stored in the Case Management System.

2. Furthermore, where a competent national authority requests Eurojust to provide it with information, Eurojust shall transmit it in the timeframe requested by that authority.;

13. in Articles 14(4) and 16(1), the words 'an index of' shall be replaced by 'a Case Management System containing';

14. in Articles 15(4), 16(1) and 16(2), the word 'index' shall be replaced by 'Case Management System' and the words 'an index' in Article 16(1) by 'a Case Management System';

15. in Article 15:

(a) in paragraph 1:

(i) the first sentence shall be replaced by:

'1. When processing data in accordance with Article 14(1), Eurojust may process personal data

on persons who, under the national legislation of the Member States concerned, are the subject of a criminal investigation or prosecution for one or more of the types of crime and the offences defined in Article 4, such as:;

(ii) the following point shall be added:

'(l) telephone numbers, vehicle registration data, e-mail accounts, phone and e-mail traffic related data, DNA records and photographs.:';

(b) in paragraph 2, the word 'only' shall be deleted;

16. the following paragraph shall be inserted in Article 16:

'2a. The Case Management System shall enable data and access to be inserted at national level. The Case Management System, insofar as this is in conformity with rules on data protection contained in this Decision, may be linked to the secure telecommunications network referred to in Article 10 of Council Decision .../.../JHA on the European Judicial Network.'

17. the following sentence shall be added at the end of Article 23(10):

'The secretariat of the Joint Supervisory Body may rely upon the expertise of the secretariat established by Council Decision 2000/641/JHA.:';

18. in Article 26

(a) the following paragraph shall be inserted:

'1a. Member States shall ensure that the College may actually be able to open a Europol Analytical Work File and that it may participate in its functioning.:';

(b) paragraph 2 shall be replaced by the following:

'2. Eurojust and the European Judicial Network shall maintain privileged relations with each other, based on consultation and complementarity, especially between the national member, the European Judicial Network contact points of the same Member State and the national correspondents for Eurojust and the European Judicial Network. In order to ensure efficient cooperation, the following measures shall be taken:

(a) Eurojust shall have access to centralised information from the European Judicial Network in accordance with Article 8 of Decision .../.../JHA and to the secured telecommunications network set up under Article 10 of the said Decision;

(b) without prejudice to Article 13 of this Decision and in accordance with Article 4(4) of Decision .../.../JHA, the contact points of the European Judicial Network shall, on a case-by-case basis, inform Eurojust on cases involving two Member States and entering the field of competence of Eurojust:

— in cases where conflicts of jurisdiction are likely to arise,

or

— in cases of a refusal of a request for judicial cooperation regarding instruments adopted under Title VI of the Treaty, including instruments giving effect to the principle of mutual recognition.

The contact points of the European Judicial Network shall, also on a case-by-case basis, inform Eurojust on all cases entering the field of competence of Eurojust and involving at least three Member States.

National members shall, on a case-by-case basis, inform European Judicial Network contact points on all cases with which the network is deemed to be in a better position to deal;

- (c) the secretariat of the European Judicial Network shall form part of the Eurojust secretariat. It shall function as a separate and autonomous unit. It may draw on the resources of Eurojust which are necessary for the performance of the European Judicial Network's tasks. The rules applying to Eurojust staff shall apply to the staff of the European Judicial Network's secretariat where this is not incompatible with the operational autonomy of the European Judicial Network's secretariat;
- (d) the European Judicial Network shall be supported by the Administration of Eurojust. Operational expenses of the European Judicial Network may be covered by the Eurojust budget in accordance with Article 33 of Decision .../.../JHA on the European Judicial Network;
- (e) the national members of Eurojust may attend meetings of the European Judicial Network at the invitation of the latter. European Judicial Network contact points may be invited on a case-by-case basis to attend Eurojust meetings;
- (f) the secretariat of the Network for Joint Investigation Teams and of the Networks set up by Decision 2002/494/JHA (war crime networks), Decision 2007/845/JHA (asset recovery offices) and any forthcoming Council decision on a contact point

network against corruption shall form part of the Eurojust secretariat and shall function as separate and autonomous units. They may draw on the resources of Eurojust which are necessary for the performance of their tasks. The rules applying to Eurojust staff shall apply to the staff of their secretariats where this is not incompatible with the operational autonomy of their secretariats; the Eurojust Administrative Director shall appoint a Secretary General, under his responsibility, of the secretariats of the Networks.;

(c) the following paragraphs shall be added:

'7. Eurojust shall establish and maintain close cooperation with the European Agency for the Management of Operational Cooperation at the External Borders (Frontex), insofar as is relevant for the performance of the tasks of Eurojust and for achieving its objectives, taking account of the need to avoid duplication of effort. The essential elements of such cooperation shall be determined by an agreement to be approved by the Council, after consultation of the Joint Supervisory Body concerning the provisions on data protection.

8. Eurojust shall establish and maintain close cooperation with the Joint Situation Centre, insofar as is relevant for the performance of the tasks of Eurojust and for achieving its objectives, taking account of the need to avoid duplication of effort. The essential elements of such cooperation shall be determined by an agreement to be approved by the Council, after consultation of the Joint Supervisory Body concerning the provisions on data protection.

9. Eurojust shall establish and maintain close cooperation with Interpol, insofar as is relevant for the performance of the tasks of Eurojust and for achieving its objectives, taking account of the need to avoid duplication of effort. The essential elements of such cooperation shall be determined by an agreement to be approved by the Council, after consultation of the Joint Supervisory Body concerning the provisions on data protection.

10. Eurojust shall establish and maintain close cooperation with the World Customs Organisation, insofar as is relevant for the performance of the tasks of Eurojust and for achieving its objectives, taking account of the need to avoid duplication of effort. The essential elements of such cooperation shall be determined by an agreement to be approved by the Council, after consultation of the Joint Supervisory Body concerning the provisions on data protection.;

19. the following Article shall be inserted:

*'Article 26a*

**Liaison Magistrates seconded to third States**

1. For the purpose of facilitating judicial cooperation, Eurojust may second liaison magistrates to a third State, subject to an agreement with the host country which shall be approved by the Council. The liaison magistrate shall be a deputy, assistant, national member of Eurojust or a magistrate seconded to Eurojust. The secondment as liaison magistrate on behalf of Eurojust shall be subject to the prior consent of the magistrate and of his Member State.

2. The liaison magistrates seconded under paragraph 1 shall be liaison magistrates for the benefit of Eurojust and the Member States' competent authorities. The activities of liaison magistrates seconded by Eurojust shall be the subject of supervision of the Joint Supervisory Body. They shall report once every year to the College of Eurojust which shall inform the Council and the European Parliament in an appropriate manner of their activities. Liaison magistrates shall also inform national members and national competent authorities of all cases concerning their Member State.

3. National competent authorities, and liaison magistrates referred to in paragraph 1, may contact each other directly. In such cases, the liaison magistrate shall inform the national member concerned of such contacts.

4. Liaison magistrates referred to in paragraph 1 shall be connected to the Case Management System.

5. The relevant expenditure of liaison magistrates seconded by Eurojust to a third State shall be regarded as operational expenditure within the meaning of Article 41(3) of the Treaty. Before negotiations are entered into with a third country, the Council shall give its approval. Eurojust shall inform the Council of any plans it has for entering into any such negotiations and the Council may draw any conclusions it sees fit.;

20. the following Articles shall be inserted:

*'Article 27a*

**Requests for judicial cooperation from third States**

1. Eurojust shall coordinate the execution of requests for judicial cooperation issued by a third State where these requests are part of the same investigation and require an execution in at least two Member States.

2. Requests referred to in paragraph 1 may be received directly by Eurojust if it is in conformity with the instruments applicable to the relationship between that third

State and the European Union or the Member States concerned.

3. Requests referred to in paragraph 1 may also be transmitted to Eurojust by a national competent authority acting either on its own initiative or because the intervention of Eurojust was requested by the third State concerned.

4. In case of urgency, the Emergency Coordination Cell referred to in Article 5a may deal with requests referred to in paragraph 1 of this Article.

*Article 27b*

**Liability**

1. Eurojust's contractual liability shall be governed by the law applicable to the contract in question.

2. In the case of non-contractual liability, Eurojust shall, independently of any liability under Article 24, make good any damage caused through the fault of the College or the staff of Eurojust in the performance of their duties regardless of the different procedures for claiming damages which exist under the law of the Member States.

3. Paragraph 2 shall also apply to damages caused through the fault of a national member in the performance of his duties, except when he is acting on the basis of the powers conferred on him pursuant to Article 9a.

4. The injured party shall have the right to demand that Eurojust refrain from taking, or drop, any action.

5. The national courts of the Member States competent to deal with disputes involving Eurojust's liability as referred to in this Article shall be determined by reference to Council Regulation (EC) No 44/2001 of 22 December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (\*).

(\*) OJ L 12, 16.1.2001, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).;

21. in Article 29:

(a) in paragraph 1, the word 'unanimously' shall be replaced by 'by a two-thirds majority';

(b) in paragraph 2, the second sentence 'It shall be renewable.' shall be replaced by 'It may be extended once without a need for a call for applications, provided that the College so decides by a three-fourths majority and appoints the Administrative Director with the same majority.';

22. Article 32 shall be amended as follows:

— the title shall be replaced by the following:

‘Informing the European Parliament, the Council and the Commission’;

— the following paragraph shall be added:

‘3. The Commission or the Council may seek Eurojust’s opinion on all draft instruments prepared under Title VI of the Treaty.’;

23. Article 33(2) shall be replaced by:

‘2. Where national members, deputies, assistants and persons in the Eurojust national coordination system act within the framework of Eurojust’s tasks, the relevant expenditure, including that on Eurojust staff, shall be regarded as operational expenditure within the meaning of Article 41(3) of the Treaty.’;

24. the following sentence shall be added at the end of Article 35(1):

‘Before forwarding the estimate to the Commission, the European Judicial Network shall be consulted in accordance with modalities defined by it.’;

25. Article 41 shall be replaced by the following:

‘Article 41

### **Reporting**

1. Member States shall inform Eurojust and the General Secretariat of the Council of any changes to national members, deputies and assistants as well as the names and contact details of persons referred to in Article 12(1) and (2). The General Secretariat shall keep an updated list of these persons and shall make their names and contact details available to all Member States and to the Commission.

2. Each Member State shall also, in accordance with Article 9a(4), when appointing its national member and at any other time if appropriate, inform Eurojust and the General Secretariat of the Council of any powers conferred on the national member in accordance with that Article.

3. The definitive appointment of a national member shall take effect on the day on which the General Secretariat of the Council receives the official notification referred to in paragraph 1.’;

26. in Article 42, the existing paragraph shall become paragraph 1 and the following paragraph shall be added:

‘2. The Commission shall at regular intervals examine the implementation by the Member States of this Decision and shall submit a report thereon to the Council together with, if appropriate, necessary proposals to improve judicial cooperation and the functioning of Eurojust. This shall in particular apply to Eurojust’s capacities to support Member States in fighting terrorism.’.

### *Article 2*

#### **Transposition**

If necessary the Member States shall bring their national law into conformity with this Decision at the earliest opportunity and in any case no later than ... <sup>(1)</sup>.

### *Article 3*

#### **Entry into force**

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, ...

*For the Council*

*The President*

...

<sup>(1)</sup> 2 years after the date of entry into force of this Decision.

**Initiative of the Republic of Slovenia, the French Republic, the Czech Republic, the Kingdom of Sweden, the Kingdom of Spain, the Kingdom of Belgium, the Republic of Poland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Slovak Republic, the Republic of Estonia, the Republic of Austria and the Portuguese Republic, with a view to adopting a Council Decision of ... on the European Judicial Network**

(2008/C 54/03)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 31 and 34(2)(c) thereof,

Having regard to the initiative of the Republic of Slovenia, the French Republic, the Czech Republic, the Kingdom of Sweden, the Kingdom of Spain, the Kingdom of Belgium, the Republic of Poland, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Slovak Republic, the Republic of Estonia, the Republic of Austria and the Portuguese Republic,

Having regard to the Opinion of the European Parliament,

Whereas:

- (1) Set up by Joint Action 98/428/JHA of 29 June 1998 <sup>(1)</sup>, the European Judicial Network has demonstrated its usefulness in the facilitation of judicial cooperation in criminal matters.
- (2) In accordance with Article 53 of the Convention of 19 June 1990 implementing the Schengen Agreement and Article 6 of the Convention of 29 May 2000 on Mutual Assistance in Criminal Matters between the Member States of the European Union, mutual legal assistance takes place through direct contacts between competent judicial authorities. This decentralisation of mutual legal assistance is now widely implemented.
- (3) The principle of mutual recognition of judicial decisions in criminal matters is implemented gradually. It not only confirms the principle of direct contacts between competent judicial authorities; it also fixes the procedures and makes them entirely judicial.
- (4) The impact of these changes to judicial cooperation was further increased by the enlargement of the European Union in 2004 and 2007. Because of this evolution, the European Judicial Network is even more necessary than at the time of its creation and must therefore be strengthened.
- (5) Eurojust was set up by Decision 2002/187/JHA <sup>(2)</sup> to improve coordination and cooperation between competent authorities of the Member States. Decision 2002/187/JHA provides that Eurojust is to maintain privileged relations with the European Judicial Network based on consultation and complementarity.

(6) Five years of coexistence of Eurojust and the European Judicial Network have demonstrated both the need to maintain the two structures and the need to clarify their relationship.

(7) It is necessary to strengthen judicial cooperation between the Member States of the European Union and to allow contact points of the European Judicial Network and Eurojust for this purpose to communicate whenever needed, directly and more efficiently through a secure telecommunications network,

HAS ADOPTED THIS DECISION:

*Article 1*

**Creation**

The network of judicial contact points set up between the Member States under Joint Action 98/428/JHA, hereinafter referred to as the 'European Judicial Network', shall continue to operate in accordance with the provisions of this Decision.

*Article 2*

**Composition**

1. The European Judicial Network shall be made up, taking into account the constitutional rules, legal traditions and internal structure of each Member State, of the central authorities responsible for international judicial cooperation and the judicial or other competent authorities with specific responsibilities within the context of international cooperation.

2. One or more contact points of each Member State shall be established in accordance with its internal rules and internal division of responsibilities, care being taken to ensure effective coverage of the whole of its territory.

3. Each Member State shall appoint, among the contact points, a national correspondent for the European Judicial Network.

4. Each Member State shall ensure that its contact points have functions in relation to judicial cooperation in criminal matters and an adequate knowledge of a language of the European Union other than its own national language, bearing in mind the need to be able to communicate with the contact points in the other Member States. Before appointing a new contact point, the Member States may seek the national correspondents' opinion.

<sup>(1)</sup> OJ L 191, 7.7.1998, p. 4.

<sup>(2)</sup> Council Decision 2002/187/JHA of 28 February 2002 setting up Eurojust with a view to reinforcing the fight against serious crime (OJ L 63, 6.3.2002, p. 1).



5. Where the liaison magistrates referred to in Joint Action 96/277/JHA <sup>(1)</sup> have been appointed in a Member State and have duties analogous to those assigned by Article 4 to the contact points, they shall be linked to the European Judicial Network and to the secure telecommunications network pursuant to Article 10 by the Member State appointing the liaison magistrate in each case, in accordance with the procedures to be laid down by that State.

6. The Commission shall designate a contact point for those areas falling within its sphere of competence.

7. The European Judicial Network shall have a Secretariat which shall be responsible for the administration of the network, in cooperation and in consultation with the Presidency of the Council. The Secretariat may represent the Network, in consultation with the Presidency.

#### Article 3

##### **Manner of operation of the network**

The European Judicial Network shall operate in particular in the following three ways:

- (a) it shall facilitate the establishment of appropriate contacts between the contact points in the various Member States in order to carry out the functions laid down in Article 4;
- (b) it shall organise periodic meetings of the Member States' representatives in accordance with the procedures laid down in Articles 5, 6 and 7;
- (c) it shall constantly provide a certain amount of up-to-date background information, in particular by means of an appropriate telecommunications network, under the procedures laid down in Articles 8, 9 and 10.

#### Article 4

##### **Functions of contact point including the national correspondent**

1. The contact points, including the national correspondent, shall be active intermediaries with the task of facilitating judicial cooperation between Member States, particularly in action to combat forms of serious crime. They shall be available to enable local judicial authorities and other competent authorities in their own country, contact points in the other countries and local judicial and other competent authorities in the other countries to establish the most appropriate direct contacts.

They may if necessary travel to meet other Member States' contact points, on the basis of an agreement between the administrations concerned.

2. The contact points, including the national correspondent, shall provide the local judicial authorities in their own country, the contact points in the other countries and the local judicial authorities in the other countries with the legal and practical

information necessary to enable them to prepare an effective request for judicial cooperation or to improve judicial cooperation in general.

3. At their respective level the contact points, including the national correspondent, shall organise training sessions on judicial cooperation for the benefit of the competent authorities of their Member State, in cooperation with the European Judicial Training Network.

#### Article 5

##### **Purposes of the periodic meetings of contact points**

1. The purposes of the periodic meetings of the European Judicial Network, to which at least two contact points per Member State shall be invited, shall be as follows:

- (a) to allow the contact points to get to know each other and exchange experience, particularly concerning the operation of the network;
- (b) to provide a forum for discussion of practical and legal problems encountered by the Member States in the context of judicial cooperation, in particular with regard to the implementation of measures adopted by the European Union.

2. The relevant experience acquired within the European Judicial Network shall be passed on to the competent European Union working parties to serve as a basis for discussion of possible legislative changes and practical improvements in the area of international judicial cooperation.

#### Article 6

##### **Frequency of plenary meetings**

The European Judicial Network plenary, composed of the national correspondents, shall meet periodically on an *ad hoc* basis, at least once a year and as its members feel the need, at the invitation of the Presidency of the Council, which shall also take account of the Member States' wishes for the Network to meet.

#### Article 7

##### **Venue of meetings**

1. Meetings may be held on the premises of the Council in Brussels, in accordance with the provisions laid down in the Council's Rules of Procedure.

2. However, alternative meetings in the Member States may be held to enable the contact points of all the Member States to meet authorities of the host State other than its contact points and visit specific bodies in that State with responsibilities in the context of international judicial cooperation or of combating certain forms of serious crime.

<sup>(1)</sup> OJL 105, 27.4.1996, p. 1.

## Article 8

**Content of the information disseminated within the European Judicial Network**

The European Judicial Network shall make the following information available to contact points and competent judicial authorities:

1. full details of the contact points in each Member State with, where necessary, an explanation of their responsibilities at national level;
2. an IT tool allowing the issuing authority of a Member State to identify the competent authority in another Member State to receive and execute its request for judicial cooperation, including European Arrest Warrants, European Evidence Warrants, orders for the freezing of assets and requests for mutual legal assistance;
3. concise legal and practical information concerning the judicial and procedural systems in the Member States;
4. the texts of the relevant legal instruments and, for conventions currently in force, the texts of declarations and reservations.

## Article 9

**Updating of information**

1. The information distributed within the European Judicial Network shall be constantly updated.
2. It shall be each Member State's individual responsibility to check the accuracy of the data contained in the system and to inform the Secretariat of the European Judicial Network immediately as soon as data on one of the four points referred to in Article 8 need to be amended.

## Article 10

**Telecommunication Tools**

1. The European Judicial Network shall ensure that:
  - (a) the information provided under Article 8 is made available on a website which is constantly updated;
  - (b) a secure telecommunications network is set up for the operational work of the contact points of the European Judicial Network;
  - (c) the secure telecommunications network makes possible the flow of data and of all requests for judicial cooperation between Member States, as well as between them and the national members, national correspondents of Eurojust and liaison magistrates appointed by Eurojust.
2. The secure telecommunications network referred to in paragraph 1 may also be used for their operational work by the national correspondents, national correspondents for terrorist matters, the national members of Eurojust and liaison magistrates appointed by Eurojust. It may be linked to the Case Management System of Eurojust referred to in Article 16 of Decision 2002/187/JHA.

## Article 11

**Relationship between the European Judicial Network and Eurojust**

1. The European Judicial Network and Eurojust shall maintain privileged relations with each other, based on consultation and complementarity, especially between the national member of Eurojust, the European Judicial Network contact points of the same Member State and the national correspondents of Eurojust and of the European Judicial Network. In order to ensure efficient cooperation the following measures shall be taken:
  - (a) Eurojust shall have access to centralised information from the European Judicial Network in accordance with Article 8 of this Decision and to the secured telecommunication network set up under Article 10 of this Decision;
  - (b) without prejudice to Article 13 of Decision 2002/187/JHA and in accordance with Article 4(4) of this Decision, the contact points of the European Judicial Network shall, on a case-by-case basis, inform Eurojust on cases involving two Member States and entering the field of competence of Eurojust:
    - in cases where conflicts of jurisdiction are likely to arise,
    - or
    - in cases of a refusal of a request for judicial cooperation, including European Arrest Warrants, European Evidence Warrants, orders for the freezing of assets and requests for mutual legal assistance;
  - (c) the contact points of the European Judicial Network shall also inform Eurojust, on a case-by-case basis, on all cases entering the field of competence of Eurojust and involving at least three Member States;
  - (d) national members shall, on a case-by-case basis, inform European Judicial Network contact points on all cases with which the network is deemed better able to deal;
  - (e) the Secretariat of the European Judicial Network shall form part of the Eurojust secretariat. It shall function as a separate and autonomous unit. It may draw on the resources of Eurojust which are necessary for the performance of the European Judicial Network's tasks. The rules applying to Eurojust staff shall apply to the staff of the European Judicial Network's secretariat where this is not incompatible with the operational autonomy of the European Judicial Network's secretariat;
  - (f) the national members of Eurojust may attend meetings of the European Judicial Network at the latter's invitation. European Judicial Network contact points may be invited on a case-by-case basis to attend Eurojust meetings.
2. The European Judicial Network shall be supported by the Administration of Eurojust. Operational expenses of the European Judicial Network may be covered by the Eurojust budget in accordance with Article 33 of Decision 2002/187/JHA.

*Article 12***Informing the Council and the Commission**

The Administrative Director of Eurojust and the Presidency of the Council shall report to the Council and the Commission in writing every second year on the activities and management, including budgetary management, of the European Judicial Network. To that end, the Presidency shall prepare a bi-annual report on the activities of the European Judicial Network and on any criminal policy problems within the Union highlighted as a result of the European Judicial Network's activities. In that report, the European Judicial Network, through the Presidency, may also make proposals for the improvement of judicial cooperation in criminal matters. The European Judicial Network may also submit any report or any other information on the operation of the European Judicial Network which may be required by the Council or the Presidency.

*Article 13***Budget**

The budget of Eurojust shall, in accordance with Article 35(1) of Decision 2002/187/JHA, include a specific part on the European Judicial Network in order for it to be able to carry out its tasks.

*Article 14***Territorial application**

As regards the United Kingdom, the provisions of this Decision shall apply to the United Kingdom of Great Britain and Northern Ireland, the Channel Islands and the Isle of Man.

*Article 15***Assessment of the operation of the European Judicial Network**

The Council shall, every four years, carry out an assessment of the operation of the European Judicial Network on the basis of a report drawn up by the Commission, in cooperation with the European Judicial Network.

*Article 16***Repeal of Joint Action 98/428/JHA**

Joint Action 98/428/JHA is hereby repealed.

*Article 17***Entry into force**

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, ...

*For the Council*

*The President*

...

---

## IV

(Notices)

## NOTICES FROM EUROPEAN UNION INSTITUTIONS AND BODIES

## COMMISSION

Euro exchange rates <sup>(1)</sup>

26 February 2008

(2008/C 54/04)

1 euro =

Currency	Exchange rate	Currency	Exchange rate		
USD	US dollar	1,4874	TRY	Turkish lira	1,7758
JPY	Japanese yen	160,45	AUD	Australian dollar	1,6048
DKK	Danish krone	7,4550	CAD	Canadian dollar	1,4722
GBP	Pound sterling	0,75360	HKD	Hong Kong dollar	11,5936
SEK	Swedish krona	9,3005	NZD	New Zealand dollar	1,8338
CHF	Swiss franc	1,6163	SGD	Singapore dollar	2,0905
ISK	Iceland króna	98,35	KRW	South Korean won	1 409,31
NOK	Norwegian krone	7,8845	ZAR	South African rand	11,3057
BGN	Bulgarian lev	1,9558	CNY	Chinese yuan renminbi	10,6468
CZK	Czech koruna	25,020	HRK	Croatian kuna	7,2812
EEK	Estonian kroon	15,6466	IDR	Indonesian rupiah	13 516,00
HUF	Hungarian forint	259,20	MYR	Malaysian ringgit	4,7790
LTL	Lithuanian litas	3,4528	PHP	Philippine peso	60,121
LVL	Latvian lats	0,6965	RUB	Russian rouble	36,2190
PLN	Polish zloty	3,5303	THB	Thai baht	45,291
RON	Romanian leu	3,6430	BRL	Brazilian real	2,5278
SKK	Slovak koruna	32,779	MXN	Mexican peso	16,0096

<sup>(1)</sup> Source: reference exchange rate published by the ECB.

## NOTICES FROM MEMBER STATES

**Information communicated by Member States regarding State aid granted under Commission Regulation (EC) No 68/2001 on the application of Articles 87 and 88 of the EC Treaty to training aid**

(Text with EEA relevance)

(2008/C 54/05)

Reference number of the aid	XT 16/08
Member State	Belgium
Region	Vlaams Gewest
Title (and/or name of the beneficiary)	Ad hoc opleidingssteun aan de NV VLAAMSE MEDIA MAATSCHAPPIJ te Vilvoorde (dossier 2007G00085)
Legal basis	Decreet betreffende het economisch ondersteuningsbeleid van 31 januari 2003 (Décret relatif à la politique d'aide économique du 31 janvier 2003)
Type of measure	Individual aid
Budget	Overall budget: EUR 0,500711 million
Maximum aid intensity	In conformity with Article 4(2)-(7) of the Regulation
Date of implementation	1.6.2007
Duration	31.5.2009
Objective	General training; Specific training
Economic sectors	Other services (NACE 92203)
Name and address of the granting authority	Agentschap Economie Afdeling Economisch Ondersteuningsbeleid Koning Albert II laan 35, bus 12 B-1030 Brussel

Reference number of the aid	XT 17/08
Member State	Belgium
Region	Vlaams Gewest
Title (and/or name of the beneficiary)	Ad hoc opleidingssteun aan de NV INEOS MANUFACTURING BELGIUM te Antwerpen (dossier 2007G00157)
Legal basis	Decreet betreffende het economisch ondersteuningsbeleid van 31 januari 2003 (Décret relatif à la politique d'aide économique du 31 janvier 2003)
Type of measure	Aid scheme
Budget	Overall budget: EUR 0,87683161 million

Maximum aid intensity	In conformity with Article 4(2)-(7) of the Regulation
Date of implementation	1.10.2007
Duration	30.9.2010
Objective	General training; Specific training
Economic sectors	Other manufacturing (NACE 23200)
Name and address of the granting authority	Agentschap Economie Afdeling Economisch Ondersteuningsbeleid Koning Albert II laan 35, bus 12 B-1030 Brussel
Reference number of the aid	XT 20/08
Member State	Germany
Region	Land Niedersachsen
Title (and/or name of the beneficiary)	Richtlinie über die Gewährung von Zuwendungen nach dem Programm „Weiterbildungsoffensive für den Mittelstand (WOM)“
Legal basis	§ 44 Landeshaushaltsordnung Niedersachsen Operationelles Programm des Landes Niedersachsen für den Europäischen Sozialfonds (ESF) in der Förderperiode 2007-2013
Type of measure	Aid scheme
Budget	Annual budget: EUR 7 million
Maximum aid intensity	In conformity with Article 4(2)-(7) of the Regulation
Date of implementation	21.12.2007
Duration	31.12.2015
Objective	General training
Economic sectors	All sectors eligible for training aid
Name and address of the granting authority	Investitions- und Förderbank Niedersachsen (NBank) Günther-Wagner-Allee 12-14 D-30177 Hannover Tel. (49-511) 300 31-0
Reference number of the aid	XT 21/08
Member State	Austria
Region	Burgenland
Title (and/or name of the beneficiary)	Richtlinien über die Schwerpunktförderung der Tourismuswirtschaft gemäß dem Landes-Wirtschaftsförderungsgesetz 1994 — WiföG.
Legal basis	Gesetz vom 24. März 1994, über Maßnahmen zur Gewährleistung der wirtschaftlichen Entwicklung im Burgenland (Landes-Wirtschaftsförderungsgesetz 1994 — WiföG), mit dem gleichzeitig das Burgenländische Tourismusgesetz 1992 geändert wird, LBGl. Nr. 33/1994, in der Fassung des Gesetzes LGBl. Nr. 64/1998
Type of measure	Aid scheme

Budget	Annual budget: EUR 0,1 million
Maximum aid intensity	In conformity with Article 4(2)-(7) of the Regulation
Date of implementation	1.1.2008
Duration	30.6.2008
Objective	General training
Economic sectors	All sectors eligible for training aid
Name and address of the granting authority	WiBAG treuhändig für das Land Burgenland Marktstraße 3 A-7000 Eisenstadt Kontaktperson: Franz Kain, Mag. Sigrid Hajek Tel. (43-5) 901 02 10 www.wibag.at

**Commission communication in the framework of the implementation of the 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**

(Text with EEA relevance)

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

(2008/C 54/06)

ESO (*)	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 556-1:2001 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices  EN 556-1:2001/AC:2006	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 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 ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	
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 ISO 10993-4:2002/A1:2006	EN 30993-4:1993  Note 3	Date expired (30.4.2003)  Date expired (31.1.2007)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for <i>in vitro</i> cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-6:2007 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	EN 30993-6:1994	Date expired (31.10.2007)
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 10993-10:2002/A1:2006	EN ISO 10993-10:1995  Note 3	Date expired (31.3.2003)  Date expired (31.1.2007)



ESO (*)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presump- tion of conformity of superseded standard (Note 1)
CEN	EN ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	EN ISO 10993-11:1995	Date expired (28.2.2007)
CEN	EN ISO 10993-12:2007 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2007)	EN ISO 10993-12:2004	31.5.2008
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 characteri- zation of materials (ISO 10993-18:2005)	—	
CEN	EN ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Require- ments for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	EN 550:1994	31.5.2010
CEN	EN ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)	EN 552:1994	30.4.2009
CEN	EN ISO 11137-2:2007 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2006, corrected version 1.8.2006)	—	
CEN	EN ISO 11138-2:2006 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	—	
CEN	EN ISO 11138-3:2006 Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	—	

ESO <sup>(1)</sup>	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 11607-1:2006 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	EN 868-1:1997	Date expired (30.4.2007)
CEN	EN ISO 11737-1:2006 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)	EN 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996	Date expired (31.10.2006)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)  EN ISO 13485:2003/AC:2007	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2009
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)
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 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	EN ISO 14971:2000	31.3.2010
CEN	EN ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)	EN 554:1994	31.8.2009
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)	—	

<sup>(1)</sup> 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.cen.eu>)

— 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 the Directive 98/34/EC of the European Parliament and of the Council <sup>(1)</sup> amended by the Directive 98/48/EC <sup>(2)</sup>.
- 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.
- This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

More information about harmonised standards on the Internet at:

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/>

---

---

<sup>(1)</sup> OJL 204, 21.7.1998, p. 37.

<sup>(2)</sup> OJL 217, 5.8.1998, p. 18.

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

(Text with EEA relevance)

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

(2008/C 54/07)

ESO (*)	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 <i>in vitro</i> diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with <i>in vitro</i> 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 556-1:2001/AC:2006	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 591:2001 Instructions for use for <i>in vitro</i> diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for <i>in vitro</i> diagnostic instruments for self-testing	—	
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 12286:1998 <i>In vitro</i> 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)
CEN	EN 12287:1999 <i>In vitro</i> diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials	—	
CEN	EN 12322:1999 <i>In vitro</i> diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media  EN 12322:1999/A1:2001	—  Note 3	Date expired (30.4.2002)

ESO (*)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presump- tion of conformity of superseded standard (Note 1)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)  EN ISO 13485:2003/AC:2007	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2009
CEN	EN 13532:2002 General requirements for <i>in vitro</i> diagnostic medical devices for self-testing	—	
CEN	EN 13612:2002 Performance evaluation of <i>in vitro</i> diagnostic medical devices	—	
CEN	EN 13640:2002 Stability testing of <i>in vitro</i> diagnostic reagents	—	
CEN	EN 13641:2002 Elimination or reduction of risk of infection related to <i>in vitro</i> diagnostic reagents	—	
CEN	EN 13975:2003 Sampling procedures used for acceptance testing of <i>in vitro</i> diagnostic medical devices — Statistical aspects	—	
CEN	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of <i>in vitro</i> diagnostic examination procedures	—	
CEN	EN 14254:2004 <i>In vitro</i> diagnostic medical devices — Single-use receptacles for the collec- tion 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 charac- terization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000)	—	
CEN	EN ISO 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	EN ISO 14971:2000	31.3.2010
CEN	EN ISO 15197:2003 <i>In vitro</i> diagnostic test systems — Requirements for blood-glucose moni- toring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)	—	
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	—	

ESO <sup>(1)</sup>	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presump- tion of conformity of superseded standard (Note 1)
CEN	EN ISO 17511:2003 <i>In vitro</i> 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 <i>In vitro</i> 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)	—	
CEN	EN ISO 20776-1:2006 Clinical laboratory testing and <i>in vitro</i> diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Reference method for testing the <i>in vitro</i> activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2006)	—	

<sup>(1)</sup> 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.cen.eu>)

— 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 CCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCC: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 the Directive 98/34/EC of the European Parliament and of the Council <sup>(1)</sup> amended by the Directive 98/48/EC <sup>(2)</sup>.

— 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.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

More information about harmonised standards on the Internet at:

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/>

<sup>(1)</sup> OJL 204, 21.7.1998, p. 37.

<sup>(2)</sup> OJL 217, 5.8.1998, p. 18.

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

(Text with EEA relevance)

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

(2008/C 54/08)

ESO (*)	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 285:2006 Sterilization — Steam sterilizers — Large sterilizers	EN 285:1996	30.11.2008
CEN	EN 375:2001 Information supplied by the manufacturer with <i>in vitro</i> diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with <i>in vitro</i> 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 455-3:2006 Medical gloves for single use — Part 3: Requirements and testing for biological evaluation	EN 455-3:1999	Date expired (30.6.2007)
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 556-1:2001/AC:2006	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 591:2001 Instructions for use for <i>in vitro</i> diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for <i>in vitro</i> 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 737-4:1998 Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems	—	

ESO (*)	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 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)
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 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	Date expired (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	—	
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 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	—	



ESO (*)	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 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)
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 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 3826-3:2007 Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features (ISO 3826-3:2006)	—	
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 5356-2:2007 Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:2006)	EN 1281-2:1995	29.2.2008
CEN	EN ISO 5360:2007 Anaesthetic vaporizers — Agent-specific filling systems (ISO 5360:2006)	EN 1280-1:1997	30.6.2008

ESO (*)	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 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	Date expired (30.6.2006)
CEN	EN ISO 7197:2006 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006)	—	
CEN	EN ISO 7376:2003 Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2003)	EN 1819:1997	Date expired (30.6.2004)
CEN	EN ISO 7396-1:2007 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)	EN 737-3:1998	30.4.2009
CEN	EN ISO 7396-2:2007 Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)	EN 737-2:1998	30.4.2009
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 7886-4:2006 Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature (ISO 7886-4:2006)	—	
CEN	EN ISO 8185:2007 Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems (ISO 8185:2007)	EN ISO 8185:1997	31.1.2008
CEN	EN ISO 8359:1996 Oxygen concentrators for medical use — Safety requirements (ISO 8359:1996)	—	
CEN	EN ISO 8536-4:2007 Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed (ISO 8536-4:2007)	—	
CEN	EN ISO 8835-2:2007 Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)	EN 740:1998	31.5.2009
CEN	EN ISO 8835-3:2007 Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)	EN 740:1998	31.5.2009
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	—	

ESO (*)	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 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 tracheos- tomized 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)
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 10328:2006 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328:2006)	—	
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	31.10.2008
CEN	EN ISO 10524-2:2006 Pressure regulators for use with medical gases — Part 2: Manifold and line pres- sure regulators (ISO 10524-2:2005)	EN 738-2:1998	31.10.2008
CEN	EN ISO 10524-3:2006 Pressure regulators for use with medical gases — Part 3: Pressure regulators inte- grated with cylinder valves (ISO 10524-3:2005)	EN 738-3:1998	31.10.2008
CEN	EN ISO 10535:2006 Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535:2006)	EN ISO 10535:1998	Date expired (30.6.2007)

ESO (*)	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 10555-1:1996 Sterile, single-use intravascular catheters — Part 1: General requirements (ISO 10555-1:1995)  EN ISO 10555-1:1996/A1:1999  EN ISO 10555-1:1996/A2:2004	—  Note 3  Note 3	Date expired (31.1.2000)  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 resusci- tators (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, carcino- genicity 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 interac- tions with blood (ISO 10993-4:2002)  EN ISO 10993-4:2002/A1:2006	EN 30993-4:1993  Note 3	Date expired (30.4.2003)  Date expired (31.1.2007)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for <i>in vitro</i> cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-6:2007 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	EN 30993-6:1994	Date expired (31.10.2007)
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 10993-10:2002/A1:2006	EN ISO 10993-10:1995  Note 3	Date expired (31.3.2003)  Date expired (31.1.2007)
CEN	EN ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	EN ISO 10993-11:1995	Date expired (28.2.2007)

ESO (*)	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 10993-12:2007 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2007)	EN ISO 10993-12:2004	31.5.2008
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 11135-1:2007 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)	EN 550:1994	31.5.2010
CEN	EN ISO 11137-1:2006 Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)	EN 552:1994	30.4.2009
CEN	EN ISO 11137-2:2007 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2006, corrected version 1.8.2006)	—	
CEN	EN ISO 11138-2:2006 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	—	
CEN	EN ISO 11138-3:2006 Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	—	
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 11140-3:2007 Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007)	EN 867-3:1997	Date expired (30.9.2007)

ESO (*)	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 11197:2004 Medical supply units (ISO 11197:2004)	EN 793:1997	Date expired (30.6.2005)
CEN	EN ISO 11607-1:2006 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	EN 868-1:1997	Date expired (30.4.2007)
CEN	EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)	—	
CEN	EN ISO 11737-1:2006 Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)	EN 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996	Date expired (31.10.2006)
CEN	EN ISO 11810-2:2007 Lasers and laser-related equipment — Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers — Part 2: Secondary ignition (ISO 11810-2:2007)	—	
CEN	EN ISO 11979-8:2006 Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements (ISO 11979-8:2006)	EN 13503-8:2000	Date expired (31.1.2007)
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 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 12322:1999 <i>In vitro</i> 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 12470-1:2000 Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device	—	

ESO (*)	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 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 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 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 13485:2003/AC:2007	EN ISO 13485:2000 EN ISO 13488:2000 EN 46003:1999	31.7.2009
CEN	EN 13544-1:2007 Respiratory therapy equipment — Part 1: Nebulizing systems and their components	EN 13544-1:2001	Date expired (31.10.2007)
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)	—	

ESO (*)	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 13718-1:2002 Air, water and difficult terrain ambulances — Part 1: Medical device interface 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	—	
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 13795-3:2006 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — Part 3: Performance requirements and performance levels	—	
CEN	EN 13824:2004 Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements	—	
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 (*)	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 14561:2006 Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area — Test method and requirements (phase 2, step 2)	—	
CEN	EN 14562:2006 Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area — Test method and requirements (phase 2, step 2)	—	
CEN	EN ISO 14602:1998 Non-active surgical implants — Implants for Osteosynthesis — Particular requirements (ISO 14602:1998)	—	
CEN	EN ISO 14607:2007 Non-active surgical implants — Mammary implants — Particular requirements (ISO 14607:2007)	—	
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 14931:2006 Pressure vessels for human occupancy (PVHO) — Multi-place pressure chamber systems for hyperbaric therapy — Performance, safety requirements and testing	—	
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)	—	

ESO (*)	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 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	EN ISO 14971:2000	31.3.2010
CEN	EN ISO 15001:2004 Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2003)	—	
CEN	EN ISO 15004-1:2006 Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)	EN ISO 15004:1997	Date expired (31.12.2006)
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 15424:2007 Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	—	
CEN	EN ISO 15747:2005 Plastics containers for intravenous injection (ISO 15747:2003)	—	
CEN	EN ISO 15883-1:2006 Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)	—	
CEN	EN ISO 15883-2:2006 Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)	—	
CEN	EN ISO 15883-3:2006 Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)	—	
CEN	EN ISO 16201:2006 Technical aids for disabled persons — Environmental control systems for daily living (ISO 16201:2006)	—	
CEN	EN ISO 17510-1:2007 Sleep apnoea breathing therapy — Part 1: Sleep apnoea breathing therapy equip- ment (ISO 17510-1:2007)	EN ISO 17510-1:2002	30.4.2008
CEN	EN ISO 17510-2:2007 Sleep apnoea breathing therapy — Part 2: Masks and application accessories (ISO 17510-2:2007)	EN ISO 17510-2:2003	30.4.2008
CEN	EN ISO 17664:2004 Sterilization of medical devices — Information to be provided by the manufac- turer for the processing of resterilizable medical devices (ISO 17664:2004)	—	
CEN	EN ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)	EN 554:1994	31.8.2009

ESO (*)	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 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 ISO 19054:2006 Rail systems for supporting medical equipment (ISO 19054:2005)	EN 12218:1998	30.6.2008
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 21171:2006 Medical gloves — Determination of removable surface powder (ISO 21171:2006)	—	
CEN	EN ISO 21534:2007 Non-active surgical implants — Joint replacement implants — Particular requirements (ISO 21534:2007)	EN 12010:1998	31.3.2008
CEN	EN ISO 21535:2007 Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants (ISO 21535:2007)	EN 12563:1998	31.3.2008
CEN	EN ISO 21536:2007 Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants (ISO 21536:2007)	EN 12564:1998	31.3.2008
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 ISO 21647:2004/AC:2006	EN 12598:1999 EN 864:1996 EN ISO 11196:1997	Date expired (31.5.2005)
CEN	EN ISO 21649:2006 Needle-free injectors for medical use — Requirements and test methods (ISO 21649:2006)	—	
CEN	EN ISO 21969:2006 High-pressure flexible connections for use with medical gas systems (ISO 21969:2005)	EN 13221:2000	Date expired (31.12.2007)
CEN	EN ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2007)	EN 12442-1:2000	30.6.2008
CEN	EN ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)	EN 12442-2:2000	30.6.2008
CEN	EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)	EN 12442-3:2000	30.6.2008

ESO <sup>(1)</sup>	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 22523:2006 External limb prostheses and external orthoses — Requirements and test methods (ISO 22523:2006)	EN 12523:1999	Date expired (30.4.2007)
CEN	EN ISO 22610:2006 Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)	—	
CEN	EN ISO 22612:2005 Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005)	—	
CEN	EN ISO 22675:2006 Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675:2006)	—	
CEN	EN ISO 23747:2007 Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)	EN 13826:2003	31.1.2008
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)

<sup>(1)</sup> 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.cen.eu>)

— 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 CCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCC: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 the Directive 98/34/EC of the European Parliament and of the Council <sup>(1)</sup> amended by the Directive 98/48/EC <sup>(2)</sup>.

— 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.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

More information about harmonised standards on the Internet at:

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/>

<sup>(1)</sup> OJL 204, 21.7.1998, p. 37.

<sup>(2)</sup> OJL 217, 5.8.1998, p. 18.

## V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF THE COMPETITION  
POLICY

COMMISSION

**Prior notification of a concentration**  
**(Case COMP/M.5073 — Scholz/TTC/GMPL JV)**  
**Candidate case for simplified procedure**

(Text with EEA relevance)

(2008/C 54/09)

1. On 20 February 2008, the Commission received a notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 <sup>(1)</sup> by which the undertakings Scholz AG ('Scholz', Germany) and Toyota Tsusho Corporation ('TTC', Japan) acquire within the meaning of Article 3(1)(b) of the Council Regulation joint control of the undertaking Green Metals Poland ('GMPL', Poland) by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are:

- for Scholz: trading and processing of ferrous and non-ferrous scrap and steel,
- for TTC: logistics services for the automotive industry, and trading of metals, machinery, chemicals and other products,
- for GMPL: collection and processing of metal and non-metal waste and scrap.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of Regulation (EC) No 139/2004. However, the final decision on this point is reserved. Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004 <sup>(2)</sup> it should be noted that this case is a candidate for treatment under the procedure set out in the Notice.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. Observations can be sent to the Commission by fax ((32-2) 296 43 01 or 296 72 44) or by post, under reference number COMP/M.5073 — Scholz/TTC/GMPL JV, to the following address:

European Commission  
Directorate-General for Competition  
Merger Registry  
J-70  
B-1049 Bruxelles/Brussel

---

<sup>(1)</sup> OJ L 24, 29.1.2004, p. 1.

<sup>(2)</sup> OJ C 56, 5.3.2005, p. 32.