

JBCE input for the RoHS FAQ document

JBCE welcomes the recast of the RoHS Directive 2011/65/EU (hereafter generally referred to as “**RoHS 2**”)¹ and appreciates the ongoing work by the Commission in realizing a comprehensive Frequently Asked Questions document (“**FAQ**”) which aims to provide further clarification and guidance to the Directive.

While the FAQ document is intended to help authorities in the Member States to interpret the Directive, the document is also highly valued by economic operators as a reference to comply with national legislation transposing the Directive.

In view of the above, JBCE would like to contribute in providing some detailed input as set out below in a Q&A form.

1. What is the scope of RoHS 2?

2. Which EEE are excluded?

- A. Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment*
- B. Large-scale stationary industrial tools*
- C. Large-scale fixed installations*
- D. Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.*

3. From when do the provisions of RoHS 2 apply?

4. What should be considered “finished EEE” under RoHS 2?

5. How should cables be treated?

6. From when can I start applying the CE mark in line with the RoHS 2 provisions?

7. Is there any information required to accompany the product which is directed towards consumers and other end-users?

¹ Similarly RoHS Directive 2002/95/EC hereafter is commonly referred to as “**RoHS 1**”.

1. What is the scope of RoHS 2?

The scope of RoHS 2 is described in Articles 2, 3 and 4 and in Annex I. RoHS 2 covers all EEE unless they are specifically excluded in Article 2.4 or Article 4.4.

2. Which EEE are excluded?

Article 2.4 states that the Directive does not apply to

- (a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
- (b) equipment designed to be sent into space;
- (c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- (d) large-scale stationary industrial tools;
- (e) large-scale fixed installations;
- (f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- (g) non-road mobile machinery made available exclusively for professional use;
- (h) active implantable medical devices;
- (i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- (j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

In view of the above following considerations should be taken into account

- A. Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment*

Equipment which is part of another type of equipment is excluded from the scope only if it fulfils all of the following conditions:

- is specifically designed and to be installed as part of another type of equipment that is excluded or does not fall within the scope of RoHS 2

- can fulfil its function only if it is part of that equipment
- can only be replaced by the same specifically designed equipment

The design of the equipment should be in such a way that its shape, surface, appearance, functionality and/or connectivity allows the equipment only to be installed as part of another type of equipment excluded or out of scope.

The condition that equipment should only function if it is part of another type of equipment should take into account normal and to be foreseen use conditions. Product descriptions and instructions on the use and operation of the equipment might clarify the purpose of and the environment in which the equipment is to be used.

Replacement only by the same specifically designed equipment should be understood as replacement by equipment with a design that equally allows the equipment product to be installed and function only as part of that same equipment. The same specifically designed equipment should however not be understood as being identical to the replaced equipment in shape, surface, appearance, functionality and/or connectivity where these characteristics are not essential in allowing the equipment only to be installed and functioning as part of another type of equipment.

Examples

- Specifically designed and fitted Audio/Visual equipment for cars, airplanes, trains, etc.
- Air conditioning equipment specifically designed and fitted for cars, airplanes, trains, etc.
- Radar equipment for ships or airplanes

B. Large-scale stationary industrial tools

Large-scale stationary industrial tools are excluded from the scope only if it fulfills all of the following conditions:

- they are a large-scale assembly of machines, equipment, and/or components
- functioning together for a specific application
- permanently installed and de-installed by professionals at a given place
- used and maintained by professionals in an industrial manufacturing facility or research and development facility;

Note:

Since above are definition of directive which is same as Current WEEE FAQ so any change on this definition will lead confusion on the market and result on short of supply of product and spare parts

C. Large-scale fixed installations

Large-scale fixed installations are excluded from the scope only if it fulfills all of the following conditions:

- they are a large-scale combination of several types of apparatus and, where applicable, other devices
- which are assembled and installed by professionals
- intended to be used permanently in a pre-defined and dedicated location
- de-installed by professionals;

The “Guide for the EMC Directive 2004/108/EC”² provides a list of examples of fixed installations.

Examples of EEE excluded from the scope:

Industrial plants, power plants, power supply networks, telecommunication networks, cable TV networks, computer networks, airport luggage handling installations, airport runway lighting installations, automatic warehouses, skating hall ice rink machinery installations, storm surge barrier installations (with the control room etc), wind turbine stations, car assembly plants, water pumping stations, water treatment plants, railway infrastructures, air conditioning installations.

D. Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

Equipment is excluded from the scope if it fulfills all of the following conditions:

- designed solely for the purposes of research and development
- only made available on a business-to-business basis

² Guide for the EMC Directive – Version 8th February 2010

http://ec.europa.eu/enterprise/sectors/electrical/files/emc_guide_updated_20100208_v3_en.pdf

Additionally Article 4.4 provides exclusions for cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

- (a) EEE placed on the market before 1 July 2006;
- (b) medical devices placed on the market before 22 July 2014;
- (c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
- (d) monitoring and control instruments placed on the market before 22 July 2014;
- (e) industrial monitoring and control instruments placed on the market before 22 July 2017;
- (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

3. From when do the provisions of RoHS 2 apply?

The provisions of RoHS 2 will apply on different dates depending on the type of EEE.

- | | |
|--|------------------|
| - For categories 1, 2, 3, 4, 5, 6, 7 and 10 | - 3 January 2013 |
| ! EEE coming into scope due to change of "dependent" | - 22 July 2019 |
| - For category 8 | |
| o In vitro diagnostic medical devices | - 22 July 2016 |
| o Other medical devices | - 22 July 2014 |
| - For category 9 | |
| o Industrial monitoring and control instruments | - 22 July 2017 |
| o Other monitoring and control instruments | - 22 July 2014 |
| - For category 11 | - 22 July 2019 |

The new definition of "dependent" is a change from the interpretation outlined in the FAQ on RoHS 1³. Under RoHS 1 it was to be understood that

- equipment was regarded dependent on electric current or electromagnetic fields if electricity was the primary energy source
- when the electric current is off, the equipment cannot fulfil its basic (primary) function
- if electrical energy is used only for support or control functions the equipment should be considered out of scope

³ Frequently Asked Questions on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)
http://ec.europa.eu/environment/waste/weee/pdf/faq_weee.pdf

1.2. What are the criteria for determining whether a product falls under the RoHS Directive? (page 4)
For the purpose of this Directive "dependent" means the equipment must be dependent on electric current or electromagnetic fields. In other words, electricity is the (e.g. not petrol or gas) primary energy.
It also means that when the electric current is off, the appliance cannot fulfil its basic (primary) function. If electrical energy is used only for support or control functions this type of equipment is not covered by Directive 2002/95/EC.

Under RoHS 2 in Article 3(2) following is specified:

(2) for the purposes of point 1, “dependent” means with regard to EEE, needing electric currents or electromagnetic fields to fulfill at least one intended function;

According Article 2.2 EEE that was outside the scope of RoHS 1, but which would not comply with RoHS 2, may nevertheless continue to be made available on the market until 22 July 2019.

4. What should be considered “finished EEE” under RoHS 2?

The Guide for the EMC Directive 2004/108/EC describes a finished appliance as “any device or unit that delivers a function and has its own enclosure”. In contrast to finished appliances, components/sub-assemblies do not, in general have a proper enclosure intended for their final use. Often they are intended to be fitted into or added to an apparatus in order to add an additional function.

Therefore although possibly subject to the substance restrictions, any device or unit that not delivers a function nor does it have its own enclosure, such as components or sub-assemblies, should not be CE marked nor have its DoC drawn up.

5. How should cables be treated?

Cables are defined in Article 3(5)

(5) “cables” means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other

Cables are subject to the substance restrictions of RoHS as set out in Article 4.1.

Cables which are placed on the market together with a specific EEE typically belong to the category of EEE which they are used with. Therefore they follow the same timeline with regard to substance restrictions as the EEE they are placed on the market together with.

The EC Blue Guide informs that “the decision whether a combination of products and parts needs to be considered as one finished product has to be taken by the manufacturer on a case-by-case basis”⁴.

Therefore as generally the CE marking as well as the drawing up of the DoC are only applied to the main product, cables placed on the market together with a specific EEE should not have its own DoC nor CE marking in view of RoHS 2, except where the manufacturer explicitly chooses so.

Where cables are separately placed on the market as spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity they should not have their own DoC nor CE marking. They remain however subject to the substance restrictions except for those cases which are explicitly excluded according to Article 4.4.:

- (a) EEE placed on the market before 1 July 2006
- (b) Medical devices placed on the market before 22 July 2014
- (c) In vitro diagnostic medical devices placed on the market before 22 July 2016
- (d) Monitoring and control instruments placed on the market before 22 July 2014
- (e) Industrial monitoring and control instruments placed on the market before 22 July 2017
- (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned

6. From when can I start applying the CE mark in line with the RoHS 2 provisions?

In line with the specified timelines in RoHS2 the CE mark should be applied, depending on the type of EEE, to the finished EEE as from following dates:

- **For categories 1, 2, 3, 4, 5, 6, 7 and 10**
 - 3 January 2013
 - 22 July 2019
- **For category 8**
 - o In vitro diagnostic medical devices - 22 July 2016
 - o Other medical devices - 22 July 2014
- **For category 9**
 - o Industrial monitoring and control instruments - 22 July 2017
 - o Other monitoring and control instruments - 22 July 2014

⁴ Guide to the Implementation of Directives based on the New Approach and the Global Approach
2.1 Products submitted to directives
http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

As the CE marking shall be affixed before the EEE is placed on the market, it is allowed to apply the CE mark before those dates, but only on the condition if the EEE already complies with the provisions of RoHS 2.

Where more than one directive is applicable, it is possible that notified bodies are involved (e.g. Medical Devices Directive⁵). Given that only one CE mark can be applied in these cases the CE marking may appear on products with an identification number, although the conformity process for RoHS 2 shall be carried out in line with to module A of Annex II to Decision No. 768/2008/EC.

7. Is there any information required to accompany the product which is directed towards consumers and other end-users?

In view of the RoHS 2 provisions there are no requirements to have any specific documentation directed towards consumers and other end-users accompanying the product (such as DoC in manual)

⁵ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF>



ABOUT JBCE

The Japan Business Council in Europe was established in 1999 as the representative organization of Japanese companies operating in the European Union. Our membership consists of more than 60 leading multinational corporations that are active across a wide range of sectors, including electronics, automotive, and chemical manufacturing. The key goal of JBCE is to contribute to EU public policy in a positive and constructive way. In doing this, we can draw upon the expertise and experience of our member companies.

JBCE input for the RoHS FAQ document

JBCE welcomes the recast of the RoHS Directive 2011/65/EU (hereafter generally referred to as “**RoHS 2**”)¹ and appreciates the ongoing work by the Commission in realizing a comprehensive Frequently Asked Questions document (“**FAQ**”) which aims to provide further clarification and guidance to the Directive.

While the FAQ document is intended to help authorities in the Member States to interpret the Directive, the document is also highly valued by economic operators as a reference to comply with national legislation transposing the Directive.

In view of the above, JBCE would like to contribute in providing some detailed input as set out below in a Q&A form.

1. What is the scope of RoHS 2?

2. Which EEE are excluded?

- A. Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment*
- B. Large-scale stationary industrial tools*
- C. Large-scale fixed installations*
- D. Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.*

3. From when do the provisions of RoHS 2 apply?

4. What should be considered “finished EEE” under RoHS 2?

5. How should cables be treated?

6. From when can I start applying the CE mark in line with the RoHS 2 provisions?

7. Is there any information required to accompany the product which is directed towards consumers and other end-users?

¹ Similarly RoHS Directive 2002/95/EC hereafter is commonly referred to as “**RoHS 1**”.

1. What is the scope of RoHS 2?

The scope of RoHS 2 is described in Articles 2, 3 and 4 and in Annex I. RoHS 2 covers all EEE unless they are specifically excluded in Article 2.4 or Article 4.4.

2. Which EEE are excluded?

Article 2.4 states that the Directive does not apply to

- (a) equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
- (b) equipment designed to be sent into space;
- (c) equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- (d) large-scale stationary industrial tools;
- (e) large-scale fixed installations;
- (f) means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- (g) non-road mobile machinery made available exclusively for professional use;
- (h) active implantable medical devices;
- (i) photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- (j) equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

In view of the above following considerations should be taken into account

- A. Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfil its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment*

Equipment which is part of another type of equipment is excluded from the scope only if it fulfils all of the following conditions:

- is specifically designed and to be installed as part of another type of equipment that is excluded or does not fall within the scope of RoHS 2

- can fulfil its function only if it is part of that equipment
- can only be replaced by the same specifically designed equipment

The design of the equipment should be in such a way that its shape, surface, appearance, functionality and/or connectivity allows the equipment only to be installed as part of another type of equipment excluded or out of scope.

The condition that equipment should only function if it is part of another type of equipment should take into account normal and to be foreseen use conditions. Product descriptions and instructions on the use and operation of the equipment might clarify the purpose of and the environment in which the equipment is to be used.

Replacement only by the same specifically designed equipment should be understood as replacement by equipment with a design that equally allows the equipment product to be installed and function only as part of that same equipment. The same specifically designed equipment should however not be understood as being identical to the replaced equipment in shape, surface, appearance, functionality and/or connectivity where these characteristics are not essential in allowing the equipment only to be installed and functioning as part of another type of equipment.

Examples

- Specifically designed and fitted Audio/Visual equipment for cars, airplanes, trains, etc.
- Air conditioning equipment specifically designed and fitted for cars, airplanes, trains, etc.
- Radar equipment for ships or airplanes

B. Large-scale stationary industrial tools

Large-scale stationary industrial tools are excluded from the scope only if it fulfills all of the following conditions:

- they are a large-scale assembly of machines, equipment, and/or components
- functioning together for a specific application
- permanently installed and de-installed by professionals at a given place
- used and maintained by professionals in an industrial manufacturing facility or research and development facility;

Note:

Since above are definition of directive which is same as Current WEEE FAQ so any change on this definition will lead confusion on the market and result on short of supply of product and spare parts

C. Large-scale fixed installations

Large-scale fixed installations are excluded from the scope only if it fulfills all of the following conditions:

- they are a large-scale combination of several types of apparatus and, where applicable, other devices
- which are assembled and installed by professionals
- intended to be used permanently in a pre-defined and dedicated location
- de-installed by professionals;

The “Guide for the EMC Directive 2004/108/EC”² provides a list of examples of fixed installations.

Examples of EEE excluded from the scope:

Industrial plants, power plants, power supply networks, telecommunication networks, cable TV networks, computer networks, airport luggage handling installations, airport runway lighting installations, automatic warehouses, skating hall ice rink machinery installations, storm surge barrier installations (with the control room etc), wind turbine stations, car assembly plants, water pumping stations, water treatment plants, railway infrastructures, air conditioning installations.

D. Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

Equipment is excluded from the scope if it fulfills all of the following conditions:

- designed solely for the purposes of research and development
- only made available on a business-to-business basis

² Guide for the EMC Directive – Version 8th February 2010

http://ec.europa.eu/enterprise/sectors/electrical/files/emc_guide_updated_20100208_v3_en.pdf

Additionally Article 4.4 provides exclusions for cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

- (a) EEE placed on the market before 1 July 2006;
- (b) medical devices placed on the market before 22 July 2014;
- (c) in vitro diagnostic medical devices placed on the market before 22 July 2016;
- (d) monitoring and control instruments placed on the market before 22 July 2014;
- (e) industrial monitoring and control instruments placed on the market before 22 July 2017;
- (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

3. From when do the provisions of RoHS 2 apply?

The provisions of RoHS 2 will apply on different dates depending on the type of EEE.

- | | |
|--|------------------|
| - For categories 1, 2, 3, 4, 5, 6, 7 and 10 | - 3 January 2013 |
| ! EEE coming into scope due to change of “dependent” | - 22 July 2019 |
| - For category 8 | |
| o In vitro diagnostic medical devices | - 22 July 2016 |
| o Other medical devices | - 22 July 2014 |
| - For category 9 | |
| o Industrial monitoring and control instruments | - 22 July 2017 |
| o Other monitoring and control instruments | - 22 July 2014 |
| - For category 11 | - 22 July 2019 |

The new definition of “dependent” is a change from the interpretation outlined in the FAQ on RoHS 1³. Under RoHS 1 it was to be understood that

- equipment was regarded dependent on electric current or electromagnetic fields if electricity was the primary energy source
- when the electric current is off, the equipment cannot fulfil its basic (primary) function
- if electrical energy is used only for support or control functions the equipment should be considered out of scope

³ Frequently Asked Questions on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)
http://ec.europa.eu/environment/waste/weee/pdf/faq_weee.pdf

1.2. What are the criteria for determining whether a product falls under the RoHS Directive? (page 4)

For the purpose of this Directive “dependent” means the equipment must be dependent on electric current or electromagnetic fields. In other words, electricity is the (e.g. not petrol or gas) primary energy.

It also means that when the electric current is off, the appliance cannot fulfil its basic (primary) function. If electrical energy is used only for support or control functions this type of equipment is not covered by Directive 2002/95/EC.

JBCE - Japan Business Council in Europe Rue de la Loi 82 B-1040 Brussels

Tel: (02) 286-5330 Fax: (02) 230-5485 E-mail: info@jbce.org

URL: <http://www.jbce.org/>

Under RoHS 2 in Article 3(2) following is specified:

(2) for the purposes of point 1, “dependent” means with regard to EEE, needing electric currents or electromagnetic fields to fulfill at least one intended function;

According Article 2.2 EEE that was outside the scope of RoHS 1, but which would not comply with RoHS 2, may nevertheless continue to be made available on the market until 22 July 2019.

4. What should be considered “finished EEE” under RoHS 2?

The Guide for the EMC Directive 2004/108/EC describes a finished appliance as “any device or unit that delivers a function and has its own enclosure”. In contrast to finished appliances, components/sub-assemblies do not, in general have a proper enclosure intended for their final use. Often they are intended to be fitted into or added to an apparatus in order to add an additional function.

Therefore although possibly subject to the substance restrictions, any device or unit that not delivers a function nor does it have its own enclosure, such as components or sub-assemblies, should not be CE marked nor have its DoC drawn up.

5. How should cables be treated?

Cables are defined in Article 3(5)

(5) “cables” means all cables with a rated voltage of less than 250 volts that serve as a connection or an extension to connect EEE to the electrical outlet or to connect two or more EEE to each other

Cables are subject to the substance restrictions of RoHS as set out in Article 4.1.

Cables which are placed on the market together with a specific EEE typically belong to the category of EEE which they are used with. Therefore they follow the same timeline with regard to substance restrictions as the EEE they are placed on the market together with.

The EC Blue Guide informs that “the decision whether a combination of products and parts needs to be considered as one finished product has to be taken by the manufacturer on a case-by-case basis”⁴.

Therefore as generally the CE marking as well as the drawing up of the DoC are only applied to the main product, cables placed on the market together with a specific EEE should not have its own DoC nor CE marking in view of RoHS 2, except where the manufacturer explicitly chooses so.

Where cables are separately placed on the market as spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity they should not have their own DoC nor CE marking. They remain however subject to the substance restrictions except for those cases which are explicitly excluded according to Article 4.4.:

- (a) EEE placed on the market before 1 July 2006
- (b) Medical devices placed on the market before 22 July 2014
- (c) In vitro diagnostic medical devices placed on the market before 22 July 2016
- (d) Monitoring and control instruments placed on the market before 22 July 2014
- (e) Industrial monitoring and control instruments placed on the market before 22 July 2017
- (f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned

6. From when can I start applying the CE mark in line with the RoHS 2 provisions?

In line with the specified timelines in RoHS2 the CE mark should be applied, depending on the type of EEE, to the finished EEE as from following dates:

- **For categories 1, 2, 3, 4, 5, 6, 7 and 10**
 - 3 January 2013
 - 22 July 2019
- **For category 8**
 - o In vitro diagnostic medical devices - 22 July 2016
 - o Other medical devices - 22 July 2014
- **For category 9**
 - o Industrial monitoring and control instruments - 22 July 2017
 - o Other monitoring and control instruments - 22 July 2014

⁴ Guide to the Implementation of Directives based on the New Approach and the Global Approach
2.1 Products submitted to directives
http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf

As the CE marking shall be affixed before the EEE is placed on the market, it is allowed to apply the CE mark before those dates, but only on the condition if the EEE already complies with the provisions of RoHS 2.

Where more than one directive is applicable, it is possible that notified bodies are involved (e.g. Medical Devices Directive⁵). Given that only one CE mark can be applied in these cases the CE marking may appear on products with an identification number, although the conformity process for RoHS 2 shall be carried out in line with to module A of Annex II to Decision No. 768/2008/EC.

7. Is there any information required to accompany the product which is directed towards consumers and other end-users?

In view of the RoHS 2 provisions there are no requirements to have any specific documentation directed towards consumers and other end-users accompanying the product (such as DoC in manual)

⁵ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF>



ABOUT JBCE

The Japan Business Council in Europe was established in 1999 as the representative organization of Japanese companies operating in the European Union. Our membership consists of more than 60 leading multinational corporations that are active across a wide range of sectors, including electronics, automotive, and chemical manufacturing. The key goal of JBCE is to contribute to EU public policy in a positive and constructive way. In doing this, we can draw upon the expertise and experience of our member companies.