

Washington, D.C.  
Los Angeles  
San Francisco  
San Diego

# McKenna & Cuneo, L.L.P.

Attorneys at Law

1900 K Street, N.W. • Washington, D.C. 20006-1108  
202-496-7500 • Fax: 202-496 7756  
<http://www.mckennacuneo.com>

Denver  
Dallas  
Brussels  
London

**TO: CRIMSON LANGUAGE SERVICES**  
**FROM: McKenna & Cuneo, L.L.P.**  
**DATE: November 6, 1998**  
**SUBJECT: Labeling of Medical Devices in the European Union**

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## **I. INTRODUCTION AND SUMMARY OF CONCLUSIONS**

This memorandum responds to your request that we outline European Union (“EU”) and certain Member States’ requirements on the labeling of medical devices and, in particular, the possible consequence of a company’s failure to label in accordance with national implementing legislation.

We discuss the relevant provisions laid down by the Medical Devices Directive 93/42/EEC of June 14, 1993 (“the Directive”), and the way it is to be implemented in some Member States. In summary, all medical devices and their accessories placed on the EU market since June 15, 1998, must comply with the essential requirements set forth by the Directive, including the CE Marking and the information and labeling requirements. These information requirements, that must be available to the user and to the patient in accordance to Annex I, point 13, to the Directive, need be expressed in the official language of the Member State where the device is to be placed.

Rather than describing the text of the Directive article by article, we present our memorandum in a more logical sequence, while making frequent reference to the appropriate Article or Annex.

## **II. DISCUSSION**

### **A. Regulatory Framework**

Council Directive 93/42/EEC<sup>1</sup> of June 14, 1993 contains the basic framework for the regulation of medical devices in the European Union. EU Directives are addressed to and binding on Member States insofar as the results to be achieved, but they must be implemented by national law in each Member State in order to be effective. Directive 93/42/EEC (“the Directive”) required implementing measures by July 1, 1994. All Member States have finally complied with the deadline, except Belgium, which is due to adopt legislation by the end of 1998. The legislation of the different Member States is important in the context of the practical impact of the Directive’s labeling requirements, particularly from a language point of view (see below, Section II.B.2.). Enforcement of the legislation is also a matter for the national authorities.

The main objective of the Directive is to harmonize national provisions with regard to the safety, health protection, and performance characteristics of medical devices, including the relevant certification and inspection procedures. These different systems created barriers to free movement of such devices within the EU’s internal market. In this light, the Directive states that all medical devices placed on the market in the EU must meet the “essential requirements” laid down in Annex I to the Directive. These requirements relate mainly to

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<sup>1</sup>Official Journal of the European Communities, No. L 169 of July 12, 1993.

design and construction of devices (for example, chemical, physical and biological properties, construction and environmental properties, protection against radiation, and information supplied by the manufacturer — including labeling — ). Companies may ensure compliance with the essential requirements in a number of different ways (full quality assurance system, product quality assurance, declaration of conformity), depending, *inter alia*, on the characteristics of the device. The company may then affix a “CE Marking”<sup>2</sup> to its device, effectively certifying that the device complies with the essential requirements. Devices bearing the CE Marking are entitled to move freely throughout the EU.

Notwithstanding the above, Article 22 of the Directive provides for an important exemption. Article 22(4) required Member States to continue to accept the placing on the market and putting into service of devices which complied with national laws in force in their territory on December 31, 1994 for a period of five years, expiring on June 14, 1998. Therefore, until recently, devices that complied with existing rules at national level could still be imported and sold in the EU. This transitional period in reality postponed the full implementation of the Directive for a further five years.

The interpretation of Article 22(4), and of the notion of “putting into service” in particular, was the subject of extensive discussions among the Member States and the European Commission in the rush toward expiration of the transitional period. This led to the adoption of a “Commission Communication on the application of the transitional provisions of Directive

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<sup>2</sup> Which simply consists of the initials “CE” - See Annex XII to the Directive, enclosed.

93/42/EEC relating to medical devices”.<sup>3</sup> This Communication clarifies the phrase “putting into service” by providing that devices which have been placed on the market (made available for use on the EU market for the first time) up to and including June 14, 1998 may, after that date, continue to be transferred to end-users and used in accordance with pre-existing national rules. This Communication is a non-binding instrument and is intended to clarify the matter until the adoption of further legislation.<sup>4</sup>

Therefore, since June 15, 1998, all medical devices placed on the EU market must bear the CE Mark and comply with the essential requirements contained in Annex I to Directive 93/42/EEC. This includes the labeling requirements described below.

**B. Labeling Requirements**

**1. Directive 93/42**

Point 13 of Annex I to the Directive sets forth the information that a manufacturer must supply with medical devices when placing them on the market in the EU. As a general principle, each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking into account the training and knowledge of the potential users. Certain details must appear on the label and others are to be included in the instructions for use. However,

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<sup>3</sup> Official Journal of the European Communities, No. C 242 of August 1, 1998.

<sup>4</sup> An amendment reflecting the Commission’s Communication is provided for in Article 21(2)(b) of the Council’s Common Position on in vitro medical devices Directive of March 23, 1998 (Official Journal of the European Communities, No. C 178 of June 6, 1998). The Council is expected to formally adopt this new legislation in the coming weeks.

instructions for use are not necessary for certain simple classes of medical devices if they can be used safely without such instructions.<sup>5</sup>

All medical devices must bear a label identifying the name or trade name and address of the manufacturer. For devices imported into the Community, the label, or the outer packaging, or instructions for use, must contain in addition the name and address of either the person responsible referred to in Article 14(2) or the authorized representative<sup>6</sup> of either the manufacturer or the importer established within the Community, as appropriate. In addition, the label must contain several further particulars, including the details strictly necessary for the user to identify the device and the contents of the packaging, as well as any operating instructions and warnings and/or precautions to take.

Point 13.4. stresses out that the manufacturer must clearly state on the label and in the instructions for use what is the purpose of the device, if that is not obvious to the user.

As for the instructions for use, they must contain several particulars, including the details required on the label, any side-effects of the device and, as a general rule, all details needed for a correct use of the device and specific precautions to be taken. In addition, where conformity with the essential requirements must be based on clinical data, as in Section I(6) of the Directive, Point 14 of the Annex requires that such data must be established in accordance with Annex X to the Directive.

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<sup>5</sup> Class I or II a.

<sup>6</sup> The definition of “authorized representative” is due to change in the near future with the adoption of the new Directive on in vitro diagnostics medical devices. See above, footnote 4.

As regards the language which must be used for the labeling and information requirements, Article 4(4) of the Directive allows Member States to “*require the information, which must be made available to the user and the patient in accordance with Annex I, point 13, to be in their national language(s) or in another Community language, when a device reaches the final user, regardless of whether it is for professional or other use*”.

Accordingly, it is for the Member States to specify in their implementing legislation which language must be used for the information on the packaging and on any label.

## **2. National implementing legislation**

In **Italy**, Law Decree n. 46 of February 24, 1997<sup>7</sup> implemented the Directive. As for language requirements on the label, Article 5(3) of the Law Decree provides that “*The information given by the manufacturer to the user and to the patient, in accordance to Annex I (13) of the Directive, must be in Italian (...)*”. (emphasis added)

The Law Decree does not specify which penalties would be applied for non-compliance to the above requirements. However, the Law Decree states that failure to comply with any information requirement is punished with fines up to 10 millions ITL and imprisonment up to six months (Article 23).

The **UK** Medical Devices Regulations 1994<sup>8</sup>, as amended, implemented the Directive and came into force in January 1<sup>st</sup>, 1995. Regulation 5 provides that devices placed on the market or put into service must comply with relevant requirements as specified in Annex I to the Directive. Under Article 5(5)a, “*the essential requirements specified in Annex I with regard*

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<sup>7</sup> Decreto Legislativo n. 46, del 24 febbraio 1997, G.U. del 6 marzo 1997, Anno 138, n. 54.

<sup>8</sup> The Medical Devices Regulations 1994 (S.I. 1994 n. 3017, Consumer Protection), as amended by AIMD Regulations 1995 (S.I. 1995/1671).

*to information on the packaging and on any label are complied with only if such information is in English (whether or not it is also in another language and whether or not the device is for professional use)*". However, with regard to the instructions for use, they may be in another EU language, provided that there is "a *clear statement in English stating the language in which instructions are given*" [Article 5(5)b]

If the product does not comply with the above requirements, Article 19(7) states that a note is sent by the authority "to *the manufacturer, or his authorized representative, warning that person that unless the requirements are met, further action may be taken*", including removal of the product from the market. In addition, "The Consumer Protection Act 1987" provides for possible further measures, including fines and imprisonment.

In **France**, Law Decree n. 95-292 of March 16, 1995<sup>9</sup>, Section 3, Article 665-11, specifically requires the French language to be used for labeling purposes. As for the enforcement, Section 9, Article 665-43, provides several sanctions for the manufacturer which places on the market an irregular product, i.e. economic sanctions and/or criminal and administrative proceedings.

Additionally, Law n. 94-43 of January 18, 1994, Section 4, Article 665-5, states that the product which does not comply with the requirements as set out by the French implementing legislation "*will be removed from the market, by order of the administrative authority*".

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<sup>9</sup> Loi n. 94-43 du 18.1.1994 (Journal Officiel du 19.1.1994, p. 960) – Decret n. 95 292 du 16.3.1995 (Journal Officiel du 17.3.1995, p. 4176).

In **The Netherlands**, Article 6(2) of the Decree on Medical Devices of March 30, 1995<sup>10</sup>, provides that “*the information referred to in the Annex I, point 13, which must be available to the patient, must be in the Dutch language*”. However, there is no mention in the Dutch implementing legislation about the penalties that would be applied in case of non-compliance of a device with the above requirements.

In **Sweden**, Law 1993:584<sup>11</sup> implemented the Directive on Medical Devices. As regards labeling requirements, Article 4, paragraph 3, of the law provides that all medical devices that are placed on the market must comply with the essential requirements set out in Annex I to the Directive. More detailed provisions are contained in a 1994 Regulation on Medical Devices<sup>12</sup>, which provides that all devices that fall under the scope of Swedish Law on Medical Devices must be labeled in Swedish (Article 9).

Penalties for non-compliance with these requirements range from the removal of the devices from the market to criminal proceedings, which may be initiated against the manufacturer. Specifically, in case of an accident caused by a medical device that does not comply with all legal requirements, civil and/or criminal proceedings are initiated against the concerned manufacturer and/or its authorized representative.

In **Denmark**, Order n. 734 of August 10, 1994 implemented the Directive on Medical Devices. Specifically, Part 2, Article 2(2) of the Order provides that “*The devices must meet the essential requirements set out in Annex I to the Directive*”. With respect to language

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<sup>10</sup> Besluit van 30 maart 1995 - Staatsblad van het koninkrijk der Nederlanden nr. 243 van 1995.

<sup>11</sup> Lagen 1993:584 om medicintekniska produkter, June 3, 1993.

<sup>12</sup> Föreskrifter och allmänna råd (SOSFS 1994:20) Medicintekniska produkter, November 28, 1994.

requirements, Article 2(4) states that *“The information set out in Annex I, Section 13, to the Directive shall be in Danish when a device reaches the final user”*. However, Article 2(4) of the Danish legislation contains some exceptions, and states that *“the National Board of Health may, however, in exceptional circumstances, allow such information to be in a language other than Danish”*.

With regard to the penalties that are imposed in case of infringement with the above requirements, Part 7, Article 17 of the Order, provides that:

*“(1) - Any infringement of sections 2,3,6,7,8,9,10,11,12,13 and 14 is an offence under this Order and shall be punishable with a fine unless the offence in question carries a more severe penalty under any other legislation.*

*(2) - Where an offence hereunder is committed by a public limited company, a private company, a cooperative society or the like, a fine may be imposed on the company or society as a body corporate [...].”*

### **III. CONCLUSIONS**

Medical device manufacturers that intend to place their products on the European market must carefully comply with all essential requirements laid down by Annex I to Directive 93/42 on Medical Devices, as well as with the Member States’ implementing legislation. With regard to language requirements, the Directive provides that Member States may require the information that accompanies a medical device to be in their national language or in another Community language. As a general rule, all Member States<sup>13</sup> require the safety information to be in their

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<sup>13</sup> The Directive was implemented in all Member States, except in Belgium.

official language and to be understandable to the final user. The penalties for non-compliance with the above requirements vary from the removal of the concerned product from the market to economic penalties and, in some cases, to criminal proceedings.

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For further information, please contact Larry R. Pilot at (202) 496-7561 or either Antoinette Long (011) 322-278-1232 or Claudio Mereu (011) 322-278-1265