MEDIMARK® EUROPE NEWS **January 2011**

# THE CERTIFICATE OF FREE SALE FOR CE-MARKED MEDICAL DEVICES

QA/RA Directors of US manufacturers of Medical Devices may receive a request from their International sales department for Certificates of Free Sale (CFS). They are effectively mandatory for the registration of CE marked devices which are not yet FDA approved in the main countries of Latin America, Asia and non-EU Eastern Europe.
In addition the CFS may need to be apostilled or legalized depending upon the concerned area. Where and how to obtain these CFS? MediMark® Europe, European authorized representative, answers to these questions for helping US QA/RA Directors to understand the process.

Who delivers CFS?
This is the National Competent Authority (NCA) of the EU member state where the manufacturer or its European Authorized Representative (EAR), for non European manufacturer, is located. It means that for US manufacturer of MDs, the QA/RA Director shall address his demand to its EAR. Then the EAR fills in a form and submits it to its NCA for approval and signature along with the CE Certificate, Design certificate if any and a Declaration of Conformity (DoC) with the name & address of the EAR. Its takes usually 3 to 6 weeks to get it back signed and stamped.

What information on the CFS?

afssaps

Saint-Denis, le 12 MARS 2010

Certificat de Libre Vente destiné à l'exportation vers les pays tiers
*Free sale certificate for exportation in the non-EC Member States*

dispositifs médicaux relevant de la directive n°93/42/CEE
*medical devices covered by Directive 93/42/EEC*

PARTIE A COMPLETER PAR LE DEMANDEUR
*Section to be completed by the applicant*

Catégorie du(des) dispositif(s) : [redacted]
*Device(s) category :*
*La désignation du(des) dispositif(s) apparaît sur la(les) déclaration(s) CE de conformité du fabricant ou du mandataire*
*The name of the device(s) appears on the EC declaration(s) of conformity of the manufacturer or the authorized representative*
Classe du(des) dispositif(s) medical(aux) : I☐ Is☐ Im☐ IIa☒ IIb☐ III☐
*Class of the medical device(s)*

Nom et adresse du fabricant ou du mandataire: MediMark® Europe Sarl. 11, rue Emile Zola - BP 2332. 38033 Grenoble Cedex 2. France
*Name and address of the manufacturer or the authorized representative : MediMark® Europe Sarl. 11, rue Emile Zola -BP 2332 38033 Grenoble Cedex 2. France*

Nom et adresse du site de production (facultatif) : [redacted] USA
*Name and address of Production site (optional):* Pulmonx Inc. [redacted] USA

Je soussigné Mr René Clément, Cogérant de MediMark Europe Sarl certifie que les informations mentionnées ci-dessus sont exactes et que les dispositifs médicaux figurant sur la déclaration CE de conformité sont marqués CE sous ma responsabilité au titre de la directive n°93/42/CEE et répondant aux exigences essentielles de santé et de sécurité
*I the undersigned Mr René Clément, Co-Chairman of MediMark Europe Sarl declare that the information above-mentioned is correct and the medical devices on the EC declaration of conformity are CE marked under my responsibility within the meaning of the European directive n°93/42/EEC and fulfil the essential requirements of health and safety*

Date 25 février 2010 Signature

Vu pour certification matérielle de la Signature de René CLEMENT
001147 14 SEP 2010
Pour le Président de la CCI de GRENOBLE Le Secrétaire

PARTIE RESERVEE A L'AFSSAPS
*Section reserved for the administration*

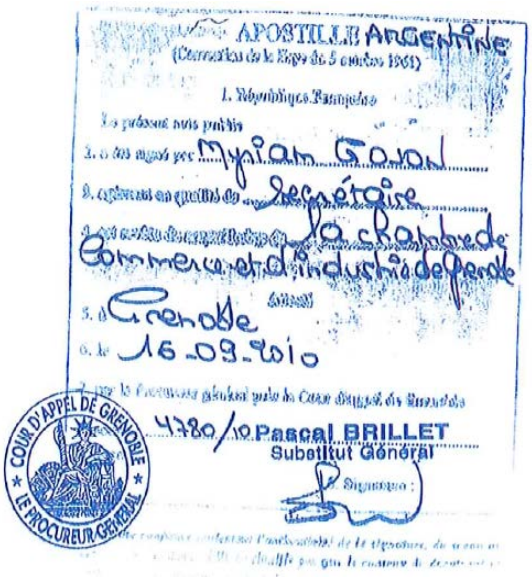
Les dispositifs médicaux marqués CE en conformité avec la directive 93/42/CEE peuvent être mis sur le marché en France et dans les autres Etats membres de la Communauté européenne, et être exportés vers les pays tiers.
Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors Union européenne.

*The medical devices EC marked in conformity with the directive 93/42/CEE can be placed on the French market and in the other Member states of the European community, and be exported to the non-EC Member States*
*This free sale certificate can only be used for exportation outside European Union*

This example of FSC delivered by AFSSAPS, the French NCA, is bilingual.
The product designation should be the one which appears on the CE certificate or on the DoC for Class1 non sterile, non measuring function MDs.
However, some countries such as Costa Rica and Ecuador are requiring currently part numbers or models included on the FSC. For Peru, it is accepted without part numbers but it is necessary to add Apostilled CE Declaration of Conformity. And in Argentina for example, it really depends of the evaluator of the register so it is important to include model numbers on it to avoid losing time and money.
These model numbers can be indicated in annex page(s) to be signed and stamped as well.
The addresses of the EAR and Manufacturer shall be indicated. The name of the EAR responsible is important because his/her signature shall be then physically certified in case of Apostil. It means that the undersigned shall go to a public Notary or, in France, to its local International Chamber of Commerce (CCI) with ID for the signature certification.

Apostilled or Legalized ?

Example of Apostil delivered in France




An Apostil can be delivered on a FSC only if destined to a country which is a Member of the Hague Conference or if having ratified the Convention of 5 October 1961 Abolishing the Requirement of Legalization for Foreign Public Documents.
The list of these countries can be found at the following website:
http://www.hcch.net/index_en.php?act=conventions.status&cid=41
Other interesting information is given such as the type of competent authority by country which delivers the Apostille, knowing that it shall be the Competent authority of the country where the FSC has been issued. For example, in France, only the Attorney General of the Court of Appeal can deliver the Apostille. It is important to mention that the destination country of the FSC shall be given for having the FSC Apostilled.

For the other countries, either the legalization is requested or the FSC delivered by the NCA without any additional stamp may suffice.
Usually an FSC is legalized for a country by its Embassy in the country where the FSC has been issued. However legalization by an Embassy in USA may be sometimes accepted.

How much it cost?
Some EU NCAS for medical devices may ask for about 50 $ per certificate. It is free in France and in UK.
Apostille is usually free of charge. Certification of the signature can be from 0 to 30 dollars.
MediMark Europe does not charge anything for its time but the EARs which charge their customers on an hourly basis will invoice the FSC.
Some Embassies may charge small fee (5-10$) for FSC Legalization. However, the practice is to use private companies specialized in legalization and which not have to stand in the line. The cost may reach 100 $ per FSC depending upon the number of documents.

Last point – Remember that CFS are not export licences; they are in effect, “letters of comfort” requested by the authorities of the importing country who are seeking assurances that the devices conform to the same quality and safety standards that apply in the European Union.

**Written by René Clément**