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Agence française de sécurité sanitaire des produits de santé

Instructions for use (IFU) for medical devices

Electronic instructions for use (IFU) for medical devices

Is it possible to use the electronic IFU rather than the paper IFU for medical devices?

The point 14 of article 11 of the directive 2007/47/CE amending the directive 93/42/CEE mentions that "the measures designed to amend non-essential elements of this Directive, by supplementing it, relating to the means by which, in the light of technical progress and considering the intended users of the devices concerned, the information laid down in Annex I Section 13.1 may be set out, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 7(3)."

Consequently, works have been engaged at European level on the modalities of implementation of an electronic IFU. Awaiting publication of these modalities, it is not possible to change the paper IFU for an other support.

Language of instructions for use (IFU) and label of medical devices, AIMDs and IVD MDs

Should the IFU and label of medical devices be written in french?

In accordance with article R. 5211-20 of the French Public Health Code (which transposed article 4 point 4 of the Directive 93/42/EEC on MDs, Directive 90/385/EEC on AIMDs and Directive 98/79/EC on IVD MDs in French law), the French state requires information, which must be available to the user and the patient in accordance with Annex I, point 13 of the Directive 93/42/EEC and with Annex I point 8 of the Directive 98/79/EC, to be in French.