THE EUROPEAN DIRECTIVE ON WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE):

Why is it relevant to medical equipment donations to low-income countries?

This document has been produced by the European working group **"MEDICAL EQUIPEMENT IN LOW-INCOME COUNTRIES"**.

OVERVIEW

In 2012, the European Parliament and the Council issued a new directive relevant to the disposal of waste electrical and electronic equipment. The full name of the directive is: **Directive 2012/19/EU on WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)**.
It replaces the Directive 2002/96/EC.

→ *http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012L0019&from=EN*

WHAT IS A EUROPEAN DIRECTIVE?

A European Directive is a legal act of the European Union that is directed at the Member States. A directive needs to be transposed into national law. This means it is required from the Member States to pass relevant domestic legislation in order to achieve the goals set out in the directive. However Member States can choose how they achieve these goals (for example, act, regulation, etc.). This transposition has to be achieved within a time frame specified in the directive itself.

What is...

ELECTRICAL AND ELECTRONIC EQUIPEMENT (EEE)?

The Directive 2012/19/UE states that EEE is "Equipment which is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields and designed for use with a voltage rating not exceeding 1 000 volts for alternating current and 1 500 volts for direct current."

WASTE ELECTRICAL AND ELECTRONIC EQUIPEMENT (WEEE)?

The Directive 2012/19/UE states that WEEE is "Electrical or electronic equipment which is waste within the meaning of article 3 of Directive 2008/98/EC, including all components, sub-assemblies and consumables which are part of the product at the time of discarding". This article 3 defines the waste as: "any substance or object which the holder discards or intends or is required to discard."

The directive is aimed at advancing the EU's environmental and sustainability agenda at a time when technology and demand are speeding up the manufacturing of all-in-one products with a programmed or short lifecycle, leading to a growing waste stream.
To address the environmental and health problems caused by this trend, the new directive sets up a European regulatory framework to promote the collection, treatment and **re-use** of electrical and electronic equipment **(RECITAL 6)** and imposes obligations for the relevant stakeholders. One feature of the directive is to mandate stricter control of the **re-use** of electrical and electronic equipment as well as of its disposal.

Medical devices are one of ten product categories of electrical and electronic equipment covered by the directive. This means the directive has **clear consequences on the re-use and transfer of medical devices** and for that reason directly concerns the aid organizations involved in the distribution of second-hand medical devices to developing countries.

Whilst a number of questions remain regarding how the directive will be interpreted and more importantly implemented in individual EU countries, the directive should have a positive impact on the **quality of medical equipment donations** to developing countries, impeaching the shipment of faulty second hand medical equipment. This still common practice, which poses a real problem as it results in unnecessary and avoidable financial and environmental costs, now seems to constitute a major concern for the European authorities. Indeed, **RECITAL 15** of the WEEE Directive clearly refers to the goal of **avoiding the shipment of faulty and/or waste electrical equipment to developing countries.**

The **ANNEX VI** entitled "Minimal requirements for shipment" is of particular relevance for aid organizations. It imposes important obligations, such as providing written proof of equipment evaluation and its proper functioning, in order to prove that it is not a WEEE. The requirements include significant obligations such as providing **written evidence of** equipment evaluation and testing which certifies the equipment functions well.

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A REGULATION TO PROMOTE THE RE-USE...

"The purpose of this directive is to contribute to sustainable production and consumption by, as a first priority, the prevention of WEEE and, in addition, by the **re-use**, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste and to contribute to the efficient use of resources and the retrieval of valuable secondary raw materials."

EXCERPT FROM RECITAL 6 // Directive 2012/19/UE

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...AND TO PREVENT THE SHIPMENT OF FAULTY EQUIPMENT

"It is appropriate to lay down minimum requirements for shipments of used EEE suspected to be WEEE [...]. Such minimum requirements should in any case have the purpose of **avoiding unwanted shipments of non-functional EEE to developing countries.**"

EXCERPT FROM RECITAL 15 // Directive 2012/19/UE

VI

WHAT NEW OBLIGATIONS MUST BE MET FOR MEDICAL EQUIPMENT DISTRIBUTION?

"In order to distinguish between EEE and WEEE, where the holder of the object claims that he intends to ship or is shipping used EEE and not WEEE, Member States shall require the holder to have available the following to substantiate this claim :

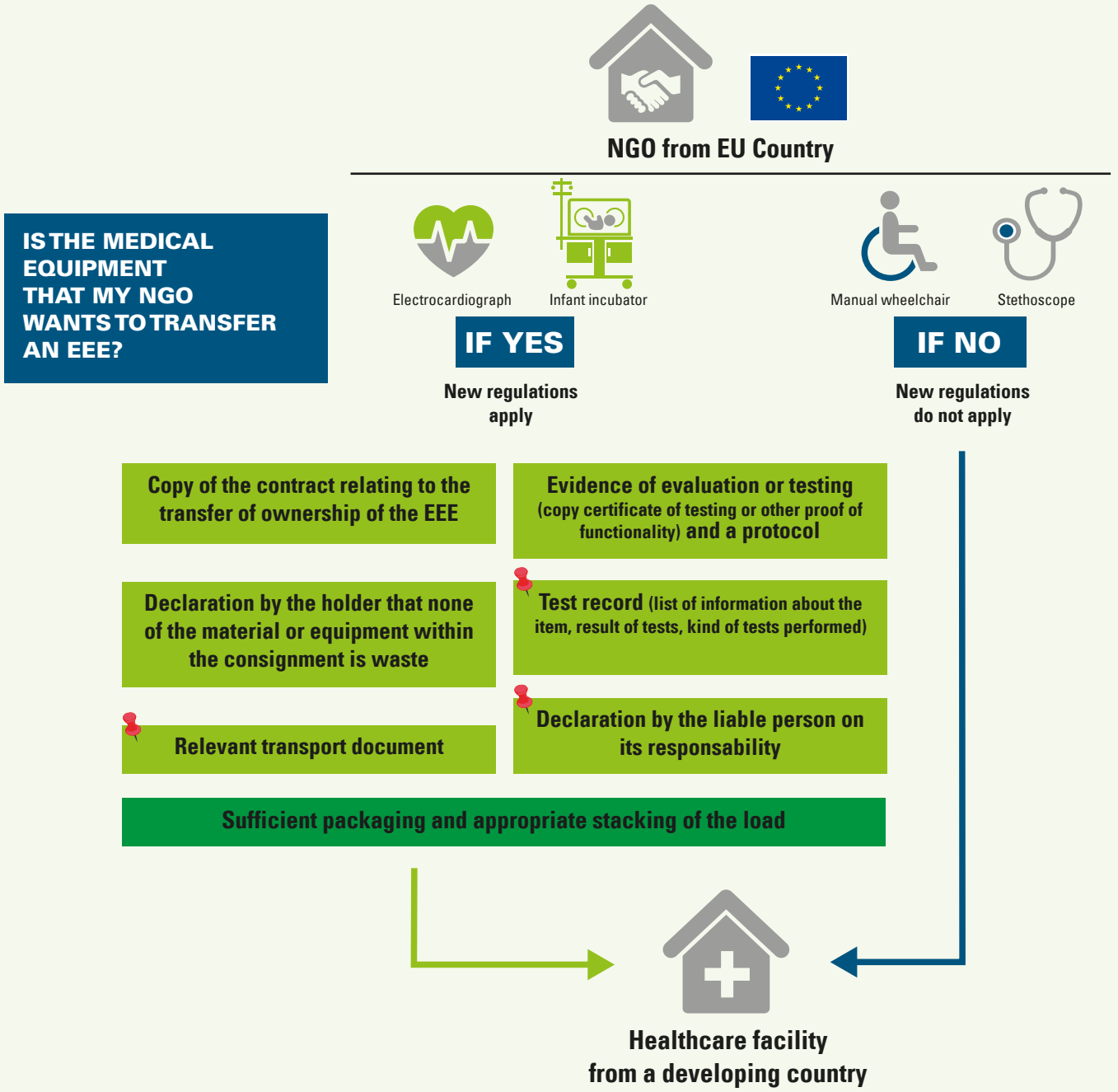
a) **a copy of the invoice and contract relating to the sale and/or transfer of ownership** of the EEE which states that the equipment is destined for direct re-use and that it is fully functional ;

(b) **evidence of evaluation or testing in the form of a copy of the records** (certificate of testing, proof of functionality) on every item within the consignment and a protocol containing all record information [...] ;

(c) **a declaration made by the holder** who arranges the transport of the EEE that none of the material or equipment within the consignment is waste [...] ;

(d) **appropriate protection against damage during transportation**, in particular, the loading and unloading through sufficient packaging and appropriate stacking of the load."

EXCERPT FROM ANNEX VI:
MINIMUM REQUIREMENTS FOR SHIPMENT // DIRECTIVE 2012/19/UE



These documents must be fixed securely on either the EEE itself or on the packaging (test record) or accompany every load (relevant transport document, declaration by the liable person on its responsability).

What steps should be taken to ensure the equipment functions effectively?

1

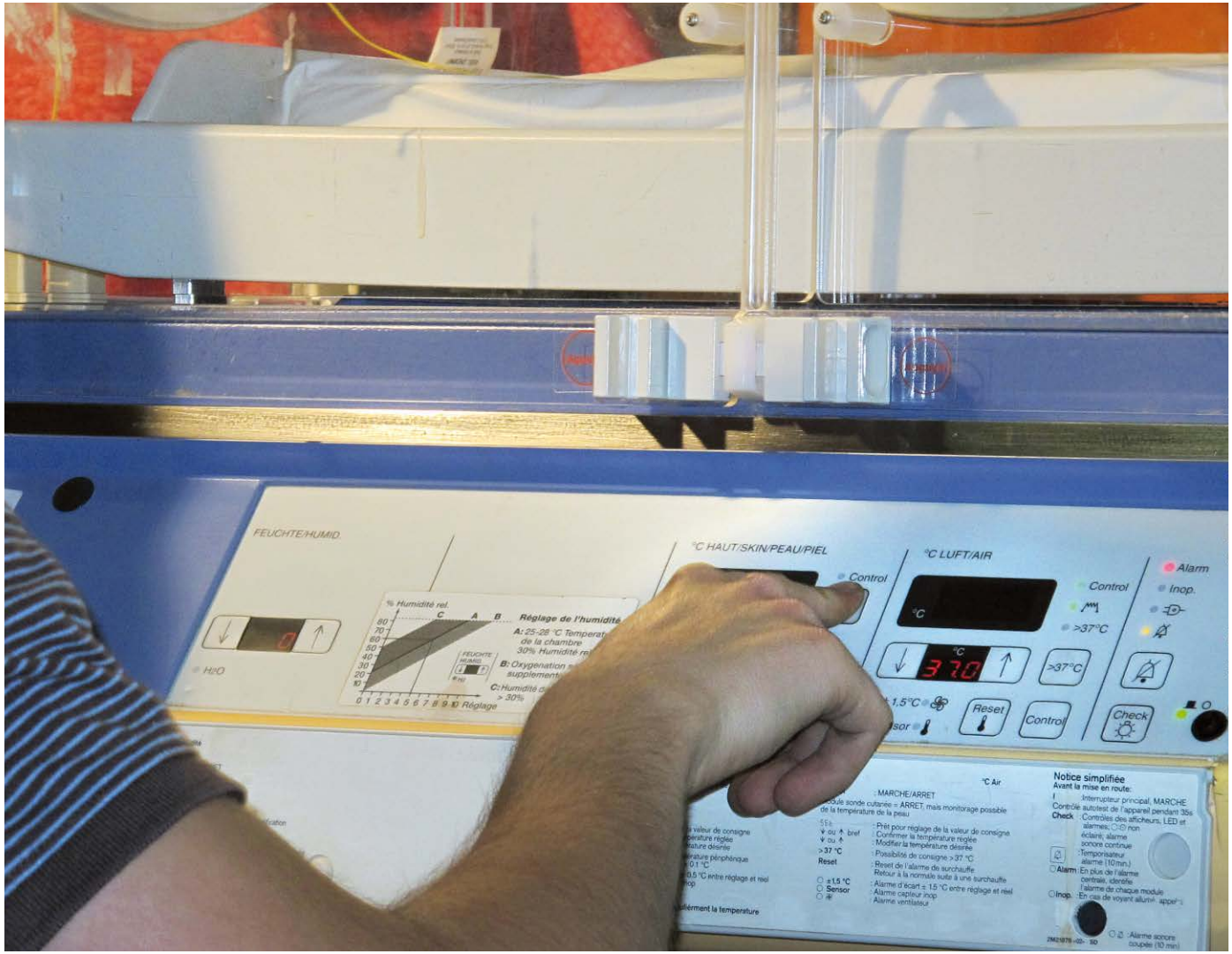
- **Test that the equipment functions properly**
- **Check for the presence of hazardous substances.**

2

- **Record the test and evaluation results.**

3

- **Fix the record securely on the EEE itself or on the packaging so it can be read without unpacking the equipment.**



SPOTLIGHT ON THE RECORD

- **Name of item** (=name of medical equipment)
- **Identification number** (=serial number)
- **Year of production**
- **Name and address of company** (or organization) responsible for evidence of functionality
- **Result of tests as described in step 1** (including date of the functionality test).

Additionally, it is important for the medical equipment holder who wants to arrange the shipment to be aware that:

• **Inspection and monitoring** are likely to be implemented by national authorities in order to meet compliance with the directive **(ARTICLE 23)**.

• **Sanctions** may occur in case of transfer of WEEE. For example, enforced return of the equipment which would be characterized as WEEE (Articles 24 and 25 of Regulation (EC) No 1013/2006, which Annex VI of the directive refers to).

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WHO WILL VERIFY COMPLIANCE WITH THE REQUIREMENTS?

"1. Member States shall carry out appropriate inspections and monitoring to verify the proper implementation of this Directive [...].

2. Member States shall ensure that shipments of used EEE suspected to be WEEE are carried out in accordance with the minimum requirements in Annex VI and shall monitor such shipments accordingly [...]".

EXCERPT FROM ARTICLE 23: INSPECTION AND MONITORING // DIRECTIVE 2012/19/UE

NATIONAL TRANSPOSITION AND ENFORCEMENT

The deadline for transposing the Directive 2012/19/EU, including the obligations laid down in Annex VI into national laws was **14 February 2014** **(ARTICLE 24)**. However, some European countries failed to transpose the Directive within the legal deadline.

The method of transposition may vary between the countries, both in regard to the number of transposing texts (some countries are transposing the directive in a single piece of legislation, others are using several documents) and in terms of the different legal instruments used for transposition (act, regulation, etc.).

The measures enacted by the national authorities for transposing the WEEE Directive are **legally binding** for stakeholders, such as **NGOs and other aid organizations** shipping medical devices to developing countries.

IMPLEMENTATION IN FRANCE

1. In which legal text(s) is the directive transposed in France?

The EU Directive was transposed into the French Code of the Environment (regulatory part) via Decree No. 2014-928 of 19 August 2014 on waste electrical and electronic equipment and on used electrical and electronic equipment.

➔ *https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000029387124&categorieLien=id*

2. Which public bodies are responsible for actually enforcing the legal national text, for example, inspecting equipment and checking documentation?

The Ministry of Ecology, Sustainable Development and Energy, the Ministry of the Economy, Industry and Digitization and the Ministry of Interior are responsible for the execution of the French decree. Inspection officers, in particular custom/border officers, as mentioned in Article L541-44 of the French Environment Code, are responsible for controlling the provisions of the decree.

3. Which public agencies or other agencies are involved in explaining and disseminating the directive/national legal text to the stakeholders and what information and communication has been provided by these organizations?

In general, a large number of French websites deal with the European Directive 2012/19/EU and Decree No. 2014-928 relating to Waste Electrical and Electronic Equipment. We provide the main examples here:

• **The European Commission** website devotes a page to the European legislation on WEEE.

➔ *http://ec.europa.eu/environment/waste/weee/index_en.htm*

• **The French Ministry of Environment, Energy and Oceans** has a dedicated web page on WEEE on its website. It refers to the EU directive and the decree, explaining the context and the issues and highlighting the main points of the Directive.

➔ *http://www.developpement-durable.gouv.fr/Dechets-d-equipements-electriques,12039.html*

• **The French Ministry of Economy and Finance** has a web page in its documentation center for the management of WEEE, which refers to Directive 2012/19/EU and Decree No. 2014-928.

➔ *http://www.economie.gouv.fr/cedef/dechets-dequipements-electriques-et-electroniques-deee*

• The **not for profit eco-organizations**, approved by the State to organize the collection, pollution control and recovery of WEEE on French territory, for example, "Eco-logic", "Récylum" and "Eco-systèmes", also devote a page of their website to the European Directive and its decree of transposition into French law.

➔ *http://www.ecologic-france.com/les-deee/reglementation-deee.html*

➔ *http://www.recylum.com/recylum/cadre-reglementaire/*

➔ *http://www.eco-systemes.fr/documentation*

• **Websites and magazines specialized in the environmental sector**, like Actu-Environnement, Environnement Magazine.fr, RSE NEWS, la Lettre des Juristes de l'Environnement, e-dechet.com have also published information (Articles, referrals, etc.) on Directive 2012/19/EU and Decree No. 2014-928.

➔ *http://www.actu-environnement.com/ae/news/deee-nouveau-dispositif-reglementaire-reprise-obligation-observatoire-23007.php4*

➔ *http://www.environnement-magazine.fr/article/11465-tout-savoir-sur-nouvelle-directive-deee/*

➔ *http://www.rsenews.com/public/dossier_envi/directive-deee.php*

➔ *http://www.juristes-environnement.com/article_detail.php?id=2011*

➔ *http://www.e-dechet.com*

• **The Franco-German Chamber of Commerce and Industry,** and more specifically its Environmental service, produced a webinar on the 11/19/2015 on the transposition of the Directive into French and German law. This was to highlight the different characteristics of the German and French systems, particularly in terms of the relevant changes exporters should now take into account.

4. Are there are any differences between the French text(s) and the directive particularly in terms of the minimum requirements for shipment?

The two major differences between the EU directive and the French decree are:

➔ The title of the French decree refers to "used EEE" (refers to second hand equipment) and WEEE, whereas the directive refers only to WEEE.

➔ The French decree provides a definition of "Equipment Holder" that is not in the directive, even though the term is used in its Annex 6.

➔ With regards to the minimum requirements for cross-border transfers of waste electrical and electronic equipment, there is no difference between the French Decree No 2014-928 and the European Directive 2012/19/EU.

5. Does the French national legal text refer to social sector organizations and NGOs involved in the reuse and/or transfer of medical equipment to developing countries?

In Decree No. 2014-928, there is no specific mention of or reference to NGOs or other organizations involved in the re-use or shipment of medical equipment. Note that in the French draft decree, there was an initial reference highlighting the reuse of EEE by social sector organisations. This endorsement was eventually removed from the decree following a review by the Council of State because the promotion of a specific type of organisation compared to other stakeholders, for example, commercial companies, implied a "political" intention which has no place in the transposition of the Directive.

6. What are the sanctions for non-compliance with the French national legal text?

Excerpt from Decree No. 2014-928: "In the absence of proof that an object is used equipment and not waste, the cargo must be processed in accordance with Articles 24 and 25 of Regulation (EC) No 1013/2006 of 14 June 2006 on shipments of equipment. In addition, the competent authority which considers the transfer to be illegal, must immediately inform the other competent authorities. (...)"

Excerpt from Regulation (EC) No 1013/2006 - Articles 24 and 25 : "If an illegal shipment is the responsibility of the notifier (= holder), WEEE should be taken by the holder or by the competent authority to be dispatched, recovered or disposed of in another way in the country of destination. The recovery or disposal must take place within thirty days or within any period as defined by the authorities in question.

If an illegal shipment is the responsibility of the consignee the competent authority of destination must ensure that the waste in question is recovered or disposed of using environmentally friendly methods by the recipient (or, if not possible, by the competent authority itself). Costs incurred in the recovery of waste of an illegal shipment, including costs of its transport, recovery or disposal, storage costs are charged to the holder or the competent authority of dispatch or destination. (...)"

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