WEEE2 guidance document:

Medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices ("MD, ivdMD & aiMD")

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Content

1 Objective

The European Commission previously published a FAQ document[1] to interpret the prerequisites of the exclusion "medical devices and in vitro diagnostic medical devices, where such devices are expected to be infective prior to end of life, and active implantable medical devices" ("MD, ivdMD & aiMD"). Unfortunately, this interpretation did not remove the possible misunderstandings in this area. Therefore, this document provides guidance and clarification for the interpretation of this exclusion for the Directive 2012/19/EU (WEEE2).

2 Definition of MD, ivdMD & aiMD subject to WEEE2

The WEEE2 directive excludes

> ***"medical devices** and **in vitro diagnostic medical devices**, where such devices **are expected to be infective prior to end of life**, and **active implantable medical devices."**[2]*

The following definitions are provided:

(i) **Medical device**, means a medical device or accessory within the meaning of, respectively, point (a) or (b) of Article 1(2) of Council Directive 93/42/EEC[3] of 14 June 1993 concerning medical devices which is EEE.

> **Accessory** means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

[1] http://ec.europa.eu/environment/waste/weee/pdf/faq.pdf concerning Directive 2012/19/EU

[2] Article 2 (4) (g), Article 3 (1) (m) (n) (o) WEEE2

[3] Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:— diagnosis, prevention, monitoring, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of. conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

(ii) **In vitro diagnostic medical device** means an in vitro diagnostic device or accessory within the meaning of, respectively, point (b) or (c) of Article 1(2) of Directive 98/79/EC[4] of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices which is EEE;

(iii) **Active implantable medical device** means an active implantable medical device within the meaning of point (c) of Article 1(2) of Council Directive 90/385/EEC of 20 June 1990[5] on the approximation of the laws of the Member States relating to active implantable medical devices which is EEE[6].

3 Interpretation of the MD, ivdMD & aiMD prerequisites

The interpretation of the above quoted exclusion follows the Commission's FAQ subject to WEEE2. EWRN provides further interpretation where the Commission´s interpretation does not lead to a clear conclusion. In detail:

Ad (i). Exclusion of medical devices and in vitro diagnostic medical devices (MD and ivdMD), where such devices are expected to be infective prior to end of life.

The expected usage of the equipment (MD and ivdMD) has to be taken into consideration to determine whether the equipment is expected to be infective prior to end of life.

If a medical device is intended to be used more than once (by one or more patients), that means it is not a single-use equipment, then this equipment is designed[7] in such a way that the risk of contamination on handling is extremely low. So, it is expected that such an equipment will reach the end of its life-span without representing a risk of public health. The exclusion applies only to single-use medical equipment and accessories (e.g. electrodes, test stripes for blood glucose meters) when they are expected to be infected prior to the end of their life.

However, there can be medical equipment that due to national regulation shall be collected and treated via an infectious health hazard regime (clinical waste).

Ad (ii). "**Active implantable medical device"** (aiMD) means that the equipment will be always infected when reaching its end of life (in case equipment has to be exchanged) and to avoid to remove the equipment from a deceased person.

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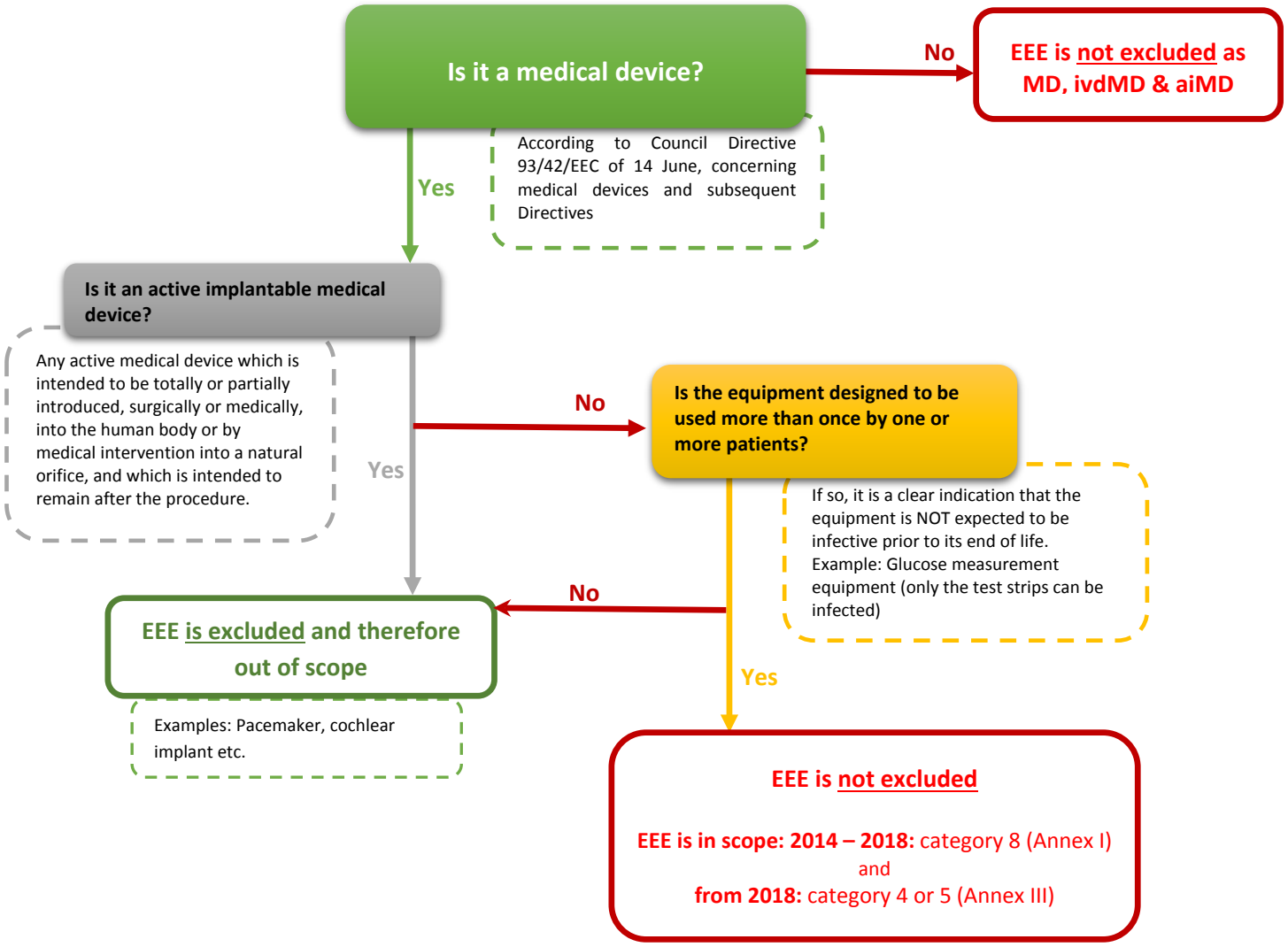
[4] Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: concerning a physiological or pathological state, or — concerning a congenital abnormality, or — to determine the safety and compatibility with potential recipients, or — to monitor therapeutic measures. Specimen receptacles are considered to be in vitro diagnostic medical devices. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;

[5] any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice , and which is intended to remain after the procedure

[6] Example: Pacemaker, FAQ RoHS, page 17

[7] Council Directive 93/42/EEC of 14 of June of 1993, concerning medical devices, Annex I – Requirements regarding design and construction, No 7 and 8.

4 Decision Tree



5 European WEEE Registers Network (EWRN)

EWRN is an independent network of national registers at the heart of the national implementation of Directive 2002/96/EC and the new Directive 2012/19/EU ("WEEE2") in the respective EU Member States.

Those responsible for managing the national registers are working together at EWRN as experts regarding electrical and electronic equipment ("EEE") and its proper treatment.

EWRNs primary objectives includes promoting a harmonised approach to registration, reporting and scoping issues across the Member States. This includes harmonised interpretation of the new exclusions under WEEE2.