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 Article 2(1) of Regulation (EU) 2017/745[3] of the European Parliament and of the Council of 5 April 2017 concerning medical devices which is EEE.

> **Accessory** within the meaning of Article 2(2) of Regulation (EU) 2017/745[4] means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s).

(ii) **In vitro diagnostic medical device** means an in vitro diagnostic medical device or accessory within the meaning of Article 2(2) and 2(4) of Regulation (EU) 2017/746[5] of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices which is EEE.

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[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] Article 2(1) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#art_2

[4] Article 2(2) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#art_2

[5] ivdMD, see Article 2(2); accessory for an ivdMD, see Article 2(4) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746#art_2

(iii) **Active implantable medical device** means an active implantable medical device within the meaning of Article 2(4) and 2(5) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017[6] on medical devices which is EEE[7].

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.

Manufacturers are required to inform users of potential risks like infectivity under Regulations (EU) 2017/745 and 2017/746. General information on the manufacturer's requirements for supplying this information is outlined in the instructions for use of the EEE.[8]

If a medical device is intended to be used more than once (by one or more patients), that means it is not single-use equipment (single-use device)[9]; this equipment is then designed[10] in such a way that the risk of contamination on handling is extremely low. So, it is expected that such equipment will reach the end of its life-span without representing a risk to public health. The exclusion applies only to single-use medical equipment and accessories (e.g. electrodes, test strips for blood glucose meters) when they are expected to be infective 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 always be infected when reaching its end of life (in case equipment has to be exchanged) and the exclusion serves to avoid removing the equipment from a deceased person.

[6] Article 2(4) and 2(5) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#art_2

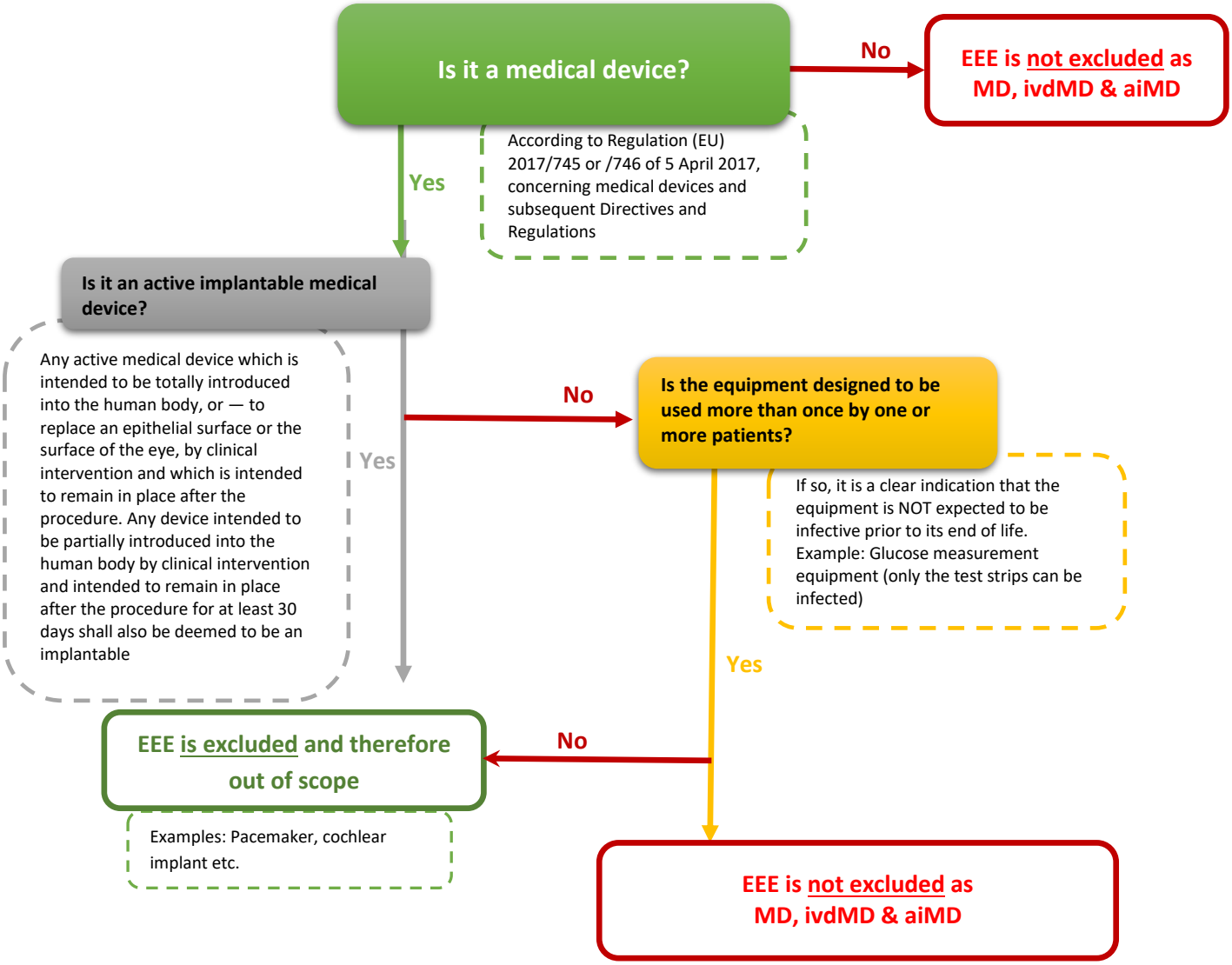
[7] Example: Pacemaker, FAQ RoHS, page 17, cf. https://environment.ec.europa.eu/document/download/051e7e21-a0cc-4cb0-a3aa-ae6cb7f13488_en?filename=FAQ key guidance document - RoHS.pdf

[8] Annex I chapter III no. 23.4. v) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#anx_I and Annex I chapter III no. 20.4. ac) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746#anx_I

[9] Annex I chapter III no. 23.2. n) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#anx_I and Annex I chapter III no. 20.2. p) of https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746#anx_I

[10] Annex I chapter III ***REQUIREMENTS REGARDING THE INFORMATION SUPPLIED WITH THE DEVICE*** in https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745#anx_I and https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746#anx_I , respectively

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.

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