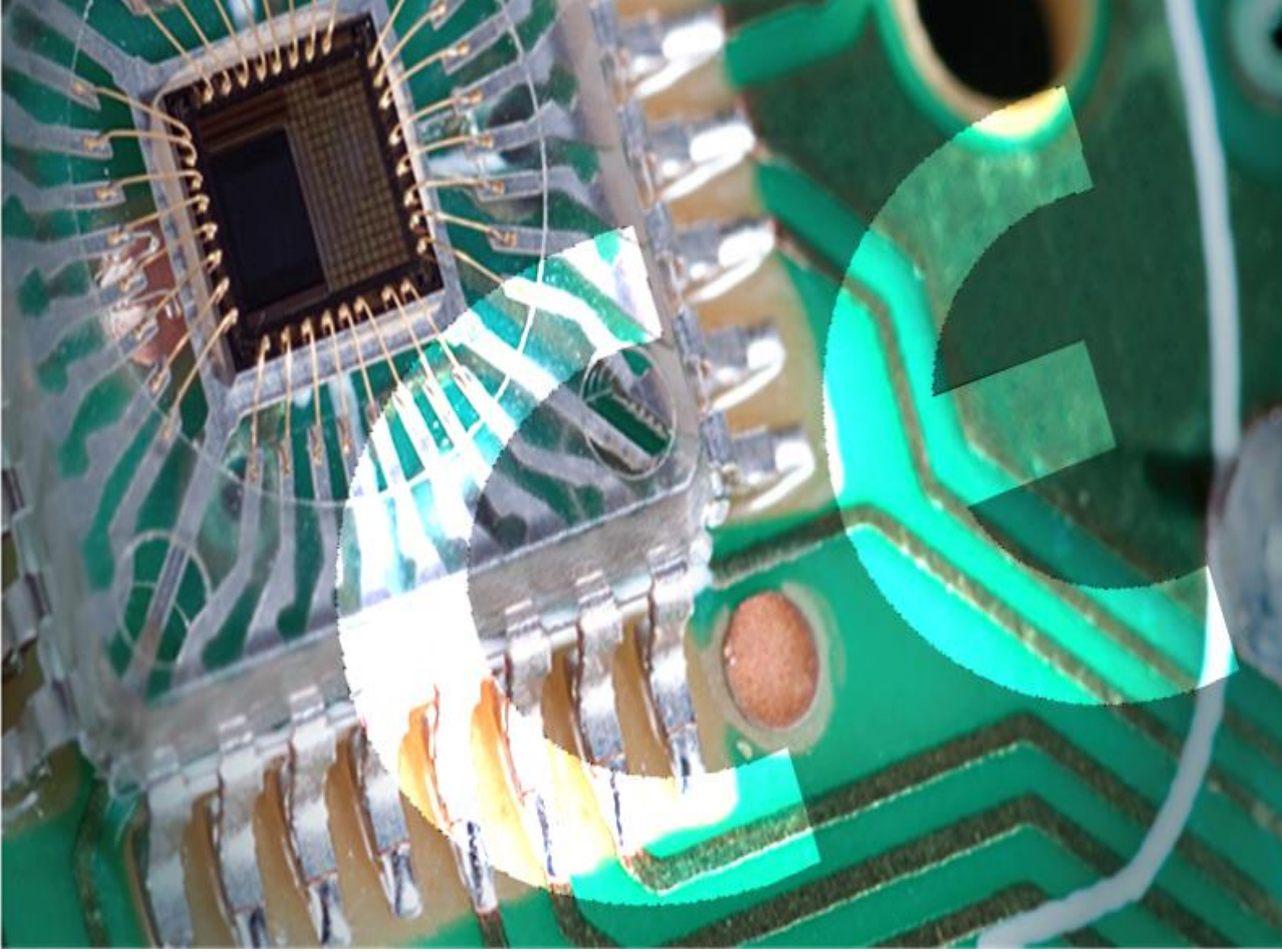

COCIR GUIDANCE

ROHS 2 OBLIGATIONS FOR COMPONENTS AND ACCESSORIES

- APRIL 2014 -

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

DISCLAIMER

This document reflects the best knowledge of industry experts across Europe and the state-of-the-art at the moment of publication. COCIR cannot be held responsible of any damage caused by the interpretations provided in this guide. Valid interpretation of Community legislation is the exclusive competence of the European Court of Justice. COCIR also recommends to producers when applying this document and its principles to always refer to the national legislation of the Member State in question.

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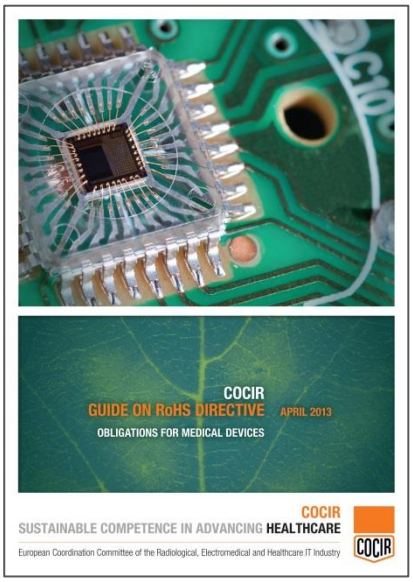
1. INTRODUCTION



The scope of the RoHS Directive is very complex and therefore it has been historically open to different interpretations. Manufacturers had to put a lot of efforts in developing guidance and common understanding of the scope provisions and in supporting such interpretations with institutions and control authorities, which sometimes came to different conclusions.

ORGALIME published several guidance documents on WEEE and RoHS scope. COCIR published one in April 2013 which deals in detail about RoHS scope applied to medical devices.

Nonetheless how RoHS obligations apply to components, parts and accessories has not been analyzed in details so far. In particular the relationship between the RoHS and MDD CE marking obligations may cause some confusion. In fact there is a mismatch between RoHS and the MDD obligations regarding CE marking. The MDD considers "finished product", to be CE marked, equipment that may be considered component by RoHS II (and therefore no marking is needed).

The objective of this guidance is to provide COCIR Members with useful indications on how to deal with different requirements applicable to medical devices, with an eye on consequences on incidental stocks of non-compliant parts and products.

2. "FINISHED PRODUCT" ACCORDING TO ROHS

RoHS I, published in 2002 and applicable since 2006, applied only to manufacturers of finished devices (which are the ones responsible for compliance) and to the finished products they placed on the market. Therefore, it did not apply to components and component manufacturers. This was quite clear looking at the definition of EEE and the list of products in Annex I. Nonetheless to solve many grey areas additional elements were needed. Following discussions between Industry and the EC the definition of "finished product" was introduced in the European Commission RoHS I FAQ (2006).

A finished product is any device or unit of equipment that has a **direct function,** its own enclosure and if applicable ports and connections intended for end users."
"Direct function"' is defined as any function of a component or a finished product which fulfils the intended use specified by the manufacturer in the instructions for use for an end user. This function can be available without further adjustment or connections other than simple ones which can be performed by any person.

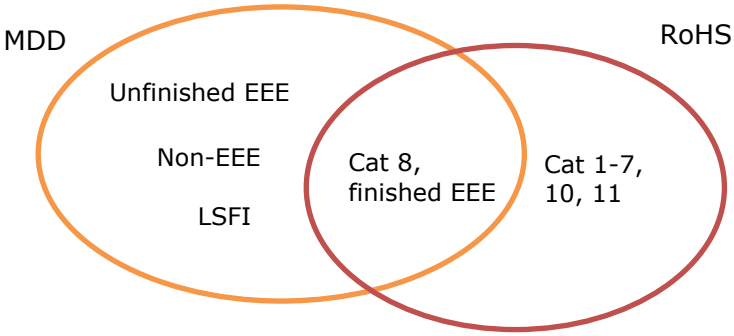
This definition was very important as, together with Annex I and the definition of EEE it allowed for a clear separation between products (finished EEE) falling into the scope of RoHS I and parts/components/subsytems (non-finished EEE) subject to RoHS obligations (substance restrictions) but not falling in the scope of the Directive itself.
Moreover, this definition is important because it does not refer at all to how the product is "placed on the market', sold to the final user or sold for further manufacturing, but is based on the very nature of the product itself.

Despite the importance of the definition and the reiterated contributions and support provided to the EC, the definition has not been taken onboard in the EC RoHS 2 FAQ. Nonetheless, the "finished product" concept is so important that it is referenced in the FAQ many times. For instance:

EU ROHS FAQ Q6.5: Are electric boards in scope?
This depends on whether the board is placed on the market as ***a finished EEE product*** *(i.e., for direct use by an end user), or it is placed on the market as a component for further production or integration into* ***a finished EEE product****. An electric panel board for use in a dwelling is a device upon which various modules (such as circuit breakers) are placed. Both the board in itself and the modules placed upon it are usually standard equipment sold to builders or home owners for direct use and so are within the scope of RoHS 2.*
Likewise graphics cards for computers are also deemed within the scope of RoHS 2 if they are supplied ***as finished products*** *and intended to perform an electrical or electronic function. Such cards, or an empty card, i.e. a card with no components or modules mounted, sold for further production or integration into* ***a finished EEE product*** *are however* ***not finished EEE themselves****.*

3. MISMATCHING CE MARKING REQUIREMENTS

Considering the different definitions in RoHS and MDD, there are different requirements for the CE marking. Not all medical devices fall under RoHS (un-finished EEE, large scale fixed installations, etc).



Therefore there can be MDs with a CE-MDD/RoHS marking and others with only the CE-MDD marking.

*NOTE: whether or not a medical device falls in both MDD and RoHS **only one CE marking is allowed**. The following abbreviations refer only to the DoC (declaration of conformity) and Technical File.*

CE-MDD: The product does not fall under RoHS (e.g. it is not electric or electronic). RoHS is not referenced in the DoC and technical file. Only the MDD is (and maybe other relevant legislation).
CE-RoHS: The product falls under RoHS but not under MDD. It is CE marked and RoHS is mentioned in the DoC and technical file
CE-MDD/RoHS: the product falls under RoHS and MDD. Both Directives are referenced in the DoC and Technical File. Only one CE marking is applied.

4. COMPONENTS, SPARE PARTS AND ACCESSORIES

The great variety of equipment in the medical device sector can be subdivided in two main categories:

1. Finished Products (i.e. MRI, CT, etc) according to the definition provided by RoHS I EC FAQs.
2. Unfinished-products (i.e. components, spare parts)

Accessories need some particular care as they can be:

1. EE (Electrical or Electronic) and finished products
2. EE and un-finished products
3. Non-EE and finished or un-finished products

4.1. COMPONENTS AND SPARE PARTS

Component is not defined in RoHS I or II. Nonetheless it is safe to say that whatever is not a finished EEE may be regarded as a component.

The terms "part", "sub-assembly", "spare part" can be considered as synonyms to "component" under RoHS. Spare part is defined by RoHS II as:

'spare part' means a separate part of an EEE that can replace a part of an EEE. The EEE cannot function as intended without that part of the EEE. The functionality of EEE is restored or is upgraded when the part is replaced by a spare part;

Components and spare parts do not need to be CE-RoHS marked. If required by the MDD they have to be CE-MDD marked. Nonetheless they have to comply with RoHS restrictions if designed to be part of a MD which falls under RoHS scope.

4.2. ACCESSORIES TO A MEDICAL DEVICE

Accessories to medical devices require special attention. An accessory is defined by Directive 93/42/EC

(b) '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;

Therefore an accessory is not necessarily a medical device and it is not necessarily a component of the equipment it is provided with (or intended to be used with). An accessory may not even be an EE (electric and electronic).

The decision flow-chart is relevant for determining if the accessory has to be RoHS compliant or not (comply with substance restriction). In case the accessory can be considered:

1. Finished product and EE, category 8 (medical device): it falls under the scope of RoHS and MDD and has to be CE-MDD/RoHS marked. [E.g. electrical drug delivery pump, battery charger for battery powered MD, MRI coils]
2. Finished product and EE, but not category 8 (medical devices): it falls under the scope of RoHS and MDD and has to be CE-MDD/RoHS marked. As it is not under category 8, application dates of RoHS obligations are different according to the category. [E.g. dosimeter for calibration of radio therapy]
3. Finished product and not EE: it does not fall under RoHS scope and does not have to comply with substance restrictions but has to be CE-MDD marked. [E.g. lead protection suit, clamps, MRI phantoms]
4. Component and EE: It does not fall under RoHS but has to comply with substance restriction. It has to be (may have to be) CE-MDD marked. [E.g. X-ray tube, power supplies, CT detectors]
5. Component and not-EE: it does not fall under RoHS scope but has to comply with substance restrictions. It has to be (may have to be) CE-MDD marked. [E.g. plastic handle, protection glass, cart wheels]

If the accessory is not a medical device itself, then it may fall in any of the categories on Annex I of RoHS and therefore the relevant obligations apply.

Cases 1-5 are summarized in the table below.

		RoHS scope	RoHS restrictions	CE-MDD	CE-RoHS	RoHS compliance
1	Finished and EE cat 8	Y	Y	Y	Y	2014
2	Finished and EEE cat 1-7, 9-11.	Y	Y	Y	Y	2006, 2017, 2019
3	Finished and not-EEE	N	N	Y	N	N.A.
4	Component and EEE	N	Y	Y/N	N	2014
5	Component and not-EEE	N	Y	Y/N	N	2014

5. SOME PARTICULAR "FINISHED PRODUCT"

Care should be taken when applying the definition of finished product, as some equipment is border-line and the "classification" may be difficult.

In particular, "plug-in" components of medical devices which can be easily switched by the user, such as ultrasound probes or RF Coils, could be considered "finished products" according to the relevant definition.
Such products can be sold separately or as specific parts/accessories of the medical device they are supposed to work with. If sold as specific parts/accessories to a medical device they have to be considered as an integral part of it and do not have to be CE-MDD/RoHS marked as all the relevant information is already included in the DoC and Tech File of the medical device.
If sold alone(not as specific part/accessories), as they are finished products, they have to be CE-MDD/RoHS marked.

5.1. SOME PRACTICAL EXAMPLE

MRI MAGNET
The MRI magnet is not a finished EEE, as it has no function on its own, but need to be integrated into other equipment (MRI). The magnet does not need to be CE-RoHS marked even if it is CE-MDD marked (as may be required by the MDD). Information about RoHS compliance of the magnet is contained in the MRI DoC and technical file.

Note: the magnet can be destined to be integrated into other types of equipment (military, LSFI, etc) which do not fall under RoHS and therefore RoHS compliance of the magnet would not be required.

X-RAY TUBE
The X-ray tube is not a finished product, as it has no function and cannot work on its own because it needs to be integrated in to an X-ray or CT machine. The tube does not need to be CE-RoHS marked even if it is already CE-MDD marked (required by MDD). Information about RoHS compliance of the X-ray tube is contained in the X-ray/CT DoC and technical file.

DIGITAL TIMER
A digital timer, which is an accessory to a medical device, is a finished EEE but does not fall under category 8 of the RoHS Directive, even if it might be considered a medical device under the MDD. Therefore, it has to be CE-RoHS/MDD marked. As for categories other than 8 and 9 RoHS entered into force in 2006, the digital timer has to be already RoHS compliant (unless, for any reason, it can be deemed to fall under category 11).

ULTRASOUND PROBES
Ultrasound probes are finished products which can be easily switched by the user according to the specific examination required. They have their own function which can be performed through simple connections and operations.

- If not sold as specific parts/components, ultrasound probes need to be CE-RoHS/MDD marked
- If sold as parts of an ultrasound equipment, probes do not need to be CE-MDD or CE-RoHS marked. All the information regarding RoHS compliance has to be reported in the ultrasound equipment DoC and Technical File.

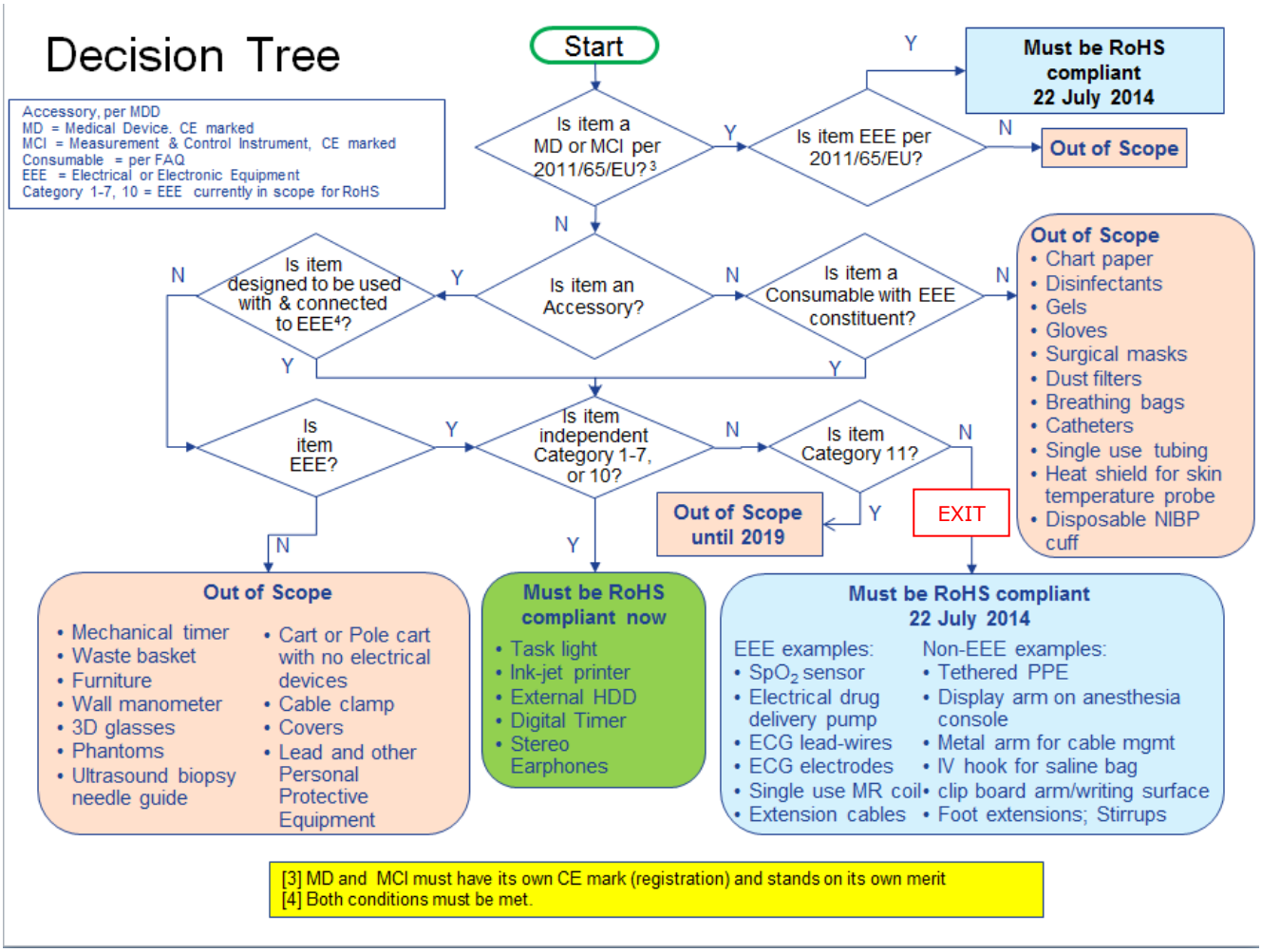
ECG ELECTRODES
ECG electrodes are finished EEE as they have they own function which can be accessed by simple connections and operations. Therefore, EGC electrodes have to be CE-RoHS/MDD marked if sold alone. If sold as specific part/component to the ECG, they do not need to be CE-RoHS/MDD marked.

MRI COILS
See ultrasound probes

DOSIMETERS FOR CALIBRATION OF RADIO-THERAPY
Dosimeters are considered as accessories to medical devices. They are finished EEE falling under category 9 of Annex I to RoHS Directive. As they are used in professional environment, they meet the definition of "industrial monitoring and control instruments". RoHS obligation applies starting from July 2017.

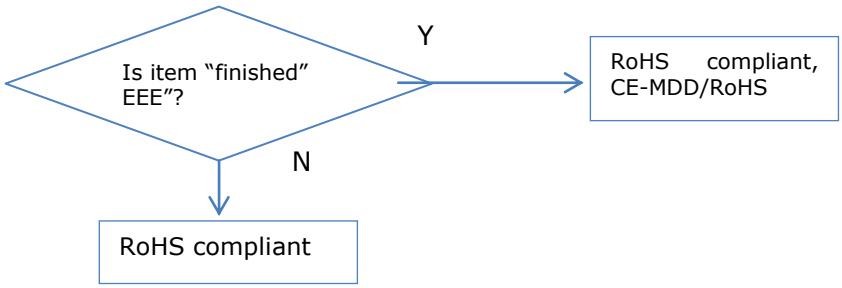
6. DECISION TREE/FLOW CHART

The decision tree is very useful and helps in deciding whether an item has to be RoHS compliant or not, meaning if it is subject to RoHS restrictions or not.



The tree does not tell if an item is subject to CE-MDD marking or to CE-MDD/RoHS marking.

Any item at EXIT should enter a new decision step:



7. STOCKS OF NON-ROHS COMPONENTS/SPARE PARTS/ACCESSORIES

From 22 July 2014, medical devices which are finished EEE cannot be placed on the EU market if not RoHS complaint.

According to RoHS II article 4.4, stocks of spare parts designed for products which are not RoHS compliant (placed on the market before July 2014) can be used for:

- Repair
- Reuse(refurbishment)
- Updating of functionalities
- Upgrading of capacity

of medical devices. Non-RoHS spare parts and components for the above listed activities can be manufactured and sold after July 2014 (but cannot be used on new RoHS compliant equipment).

8. FINISHED EQUIPMENT / SPARE PARTS

Under specific circumstances, finished EEE designed to be used with medical devices, such as ultrasound probes or MRI coils, can be considered spare parts. They are not placed on the market but are supplied as spare parts to maintain installed equipment or for further manufacturing/assembly into other equipment. Spare parts have to be classified as such by the manufacturer (with a specific part number).

As they are non-RoHS compliant spare parts designed for non-RoHS compliant medical devices placed on the market before July 2014, whether manufactured or in the stock of the manufacturer, they can be supplied after July 2014 for the servicing, maintenance and repair of non-RoHS complaint medical devices. As they are considered spare parts, and classified as such by the manufacturer, such products should not be CE-RoHS/MDD marked.

9. UPGRADE SETS / KITS

Manufacturers offer, as part of their medical device product configuration, options and upgrade kits with the aim of supplying medical device products that meet healthcare professionals' needs (e.g. those with a high number of patients, those wishing to have additional or different display or storing of images, with a distinctive patient group, with facilities of different sizes, with specific working methodologies, etc.).

Some of those are finished EEE and within categories 1-7 and 10 of RoHS (E.g. printers, monitors) therefore they should already comply with RoHS substance restrictions and CE mark requirements.

There are items that are specifically designed by the manufacturer as components to a specific medical device model to add onto its functionality. Whether or not EEE, such components are not finished products. Therefore, manufacturers are allowed to supply non-RoHS compliant versions for specific non-RoHS medical devices placed on the market before July 22, 2014, as defined by article RoHS II article 4.4:

> 4. Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:
> ……
> (b) medical devices placed on the market before 22 July 2014;
> ……

10. CONSUMABLES

Consumables are not equipment by definition. In fact they are supposed to be consumed/depleted and discarded when they fulfilled their function. Consumables, such as filtering cartridges, paper sheets, U/S gel, EGC cables (one time usage), etc. do not fall into the scope of RoHS even if provided with a Medical Device.

11. ROHS EXEMPTION FOR RECOVERED SPARE PARTS

On 9 January 2014 a new exemption, submitted by COCIR in 2012 was published on the Official Journal as a Commission Delegated Directive 2014/15/EU

'31. Lead, cadmium and hexavalent chromium in reused spare parts, recovered from medical devices placed on the market before 22 July 2014 and used in category 8 equipment placed on the market before 22 July 2021, provided that reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts is notified to the consumer. Expires on 21 July 2021.'

This exemption allow companies to reuse non-RoHS spare parts which have been recovered from old non-RoHS medical devices to repair, reuse, update or upgrade RoHS-compliant medical devices placed on the market after July 2014 and also to manufacture new RoHS medical devices as long as the conditions are met.

The wording of the exemption presents some limitations:

- Parts recovered from medical devices placed on market outside the EU before July 2014 cannot be reused.
- PBB, PBDE and Mercury, while probably not used in medical devices, may be present in old spare parts. Therefore such parts can be used only if the manufacturer can prove (or collect appropriate info) that such substances are not used.

Considering how important such exemption are for refurbishment activities of medical devices, COCIR submitted in February 2014 another request to the European commission, asking for the exemption to be amended.

COCIR proposed:

"…… lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially recovered from medical devices placed on the global market before 22 July 2014 and used in category 8 equipment placed on the market before July 22 2021 and lead, cadmium, hexavalent chromium, mercury, PBB and PBDE in reused parts initially* recovered from in-vitro medical devices placed on the global market before 22 July 2016 and used in category 8 equipment placed on the market before July 22 2023 ; provided that use and reuse takes place in auditable closed-loop business-to-business return systems, and that the reuse of parts are notified to the consumer. "Placed on the global market" means making available for the first time globally".*

**initially: refurbished parts can be reused multiple times (also in products sold after 07-22-2014). This exemption shall also apply for parts recovered from products sold after 07-22-2014, if the recovered part was initially placed in a product sold before 07-22-2014.*