Exemption Renewal Form - Exemption 31a Annex IV

Date of submission: **02 January 2020**

Attached documentation:

- **REG0364001 COCIR RoHS exemption 31a LCA assessment report**

1. Name and contact details

1) Name and contact details of applicant

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Function:	**EHS Policy Senior Manager**	Address:	**Blvd A. Reyers 80, 1030 Bruxelles**

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2. Reason for application:

Please indicate where relevant:

- ☐ Request for new exemption in:
- ☐ Request for amendment of existing exemption in
- ☒ Request for extension of existing exemption in Annex IV
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: **31a**

Proposed or existing wording: **Lead, cadmium, hexavalent chromium, and deca-brominated diphenyl ethers (deca-BDE) in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, or electron microscopes and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer.**

Expires on:

(a) 21 July 2028 for the use in medical devices other than in vitro diagnostic medical devices;

(b) 21 July 2030 for the use in vitro diagnostic medical devices

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Medical devices are frequently refurbished by the original manufacturer for reuse after they have been used by first users. Many refurbished medical devices are sold in the EU as EU hospitals have limited budgets and refurbished equipment provides the capability that they need and the lower prices allows hospitals to buy additional medical equipment and therefore offer a better healthcare to patients. Refurbishment uses recovered spare parts (which have also been refurbished themselves) as using new parts is not an option because they are no longer produced. Recovered and refurbished parts are also reused as spare parts for repair and maintenance of the installed base in the EU. Reuse of only some parts is permitted by RoHS without exemption 31a so that without this exemption, reused parts cannot be used in the EU as it is not possible to know if the part is covered by an exclusion or not.

Reuse of parts is always preferable to disposal as waste and manufacture of a replacement part. The overall health and environmental impact of reuse is shown, using life cycle assessments, to be significantly smaller than the overall impacts from disposal of parts as waste and manufacture of a replacement parts. There are also qualitative human health impacts, if limitations occur for the refurbishment market. Delays in hospitals being not able to afford new replacement equipment mean that old less reliable equipment has to be used for a longer time, or delays to treatment would be caused, if bigger upgrades (including making new replacement parts) would need to be performed, because adequate spare parts are not available.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: Medical Imaging Devices (e.g. MRI, CT, PET, SPECT, ultrasound imaging, X-Ray systems, dialysis pumps) and in-vitro diagnostic (IVD) medical devices.

a. List of relevant categories: (mark more than one where applicable)

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☐ 9
☐ 4	☐ 10

☐ 5 ☐ 11
☐ 6

b. Please specify if application is in use in other categories to which the exemption request does not refer: Category 9

c. Please specify for equipment of category 8 and 9:
The requested exemption will be applied in
☐ monitoring and control instruments in industry
☒ in-vitro diagnostics
☒ other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?
(Indicate more than one where applicable)

☒ Pb ☒ Cd ☐ Hg ☒ Cr-VI ☐ PBB ☒ PBDE (Deca-BDE)

3. Function of the substance: Lead in solders and solderable coatings, hexavalent chromium in passivation coatings, cadmium in coatings and in plastics for applications excluded from the REACH Regulation's restriction and deca-BDE as a flame retardant. Also RoHS substances in applications that had been previously exempted under RoHS Annex III and IV.

4. Content of substance in homogeneous material (%weight):

Typical examples of concentrations are approximately:

- Pb in solder and in solder-able coatings ca. 2 – 40%,
- **Lead** in alloys: 4 – 10% in copper alloys and 0.4 - 2% in aluminium alloys, e.g. used as bearings (e.g. in motors) and in gearboxes,
- CrVI in passivation coatings 1 – 30%,
- Cd pigments (in applications excluded from REACH) 1 - 50%,
- Deca-BDE flame retardant 3 – 8%

Note that penta-BDE and octa-BDE were used in electrical equipment until these substances were banned by the REACH Regulation in 2004 and so will no longer occur in recovered parts. The only PBDE flame retardant that has been used in medical devices until 2014 was deca-BDE.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Zero - No net change in amount within the EU

Please supply information and calculations to support stated figure.

All parts that have been produced for medical devices after 21 July 2014 and after 21 July 2016 for In-Vitro-Diagnostic Medical Devices (IVD MD) will not contain RoHS restricted substances, except in applications which had previously been exempted under RoHS Annex III and IV. However recovered parts from older equipment may contain these substances. Some non-EU parts (recovered from pre-2014 medical devices /from pre-2016 in-Vitro-Diagnostic devices that were originally sold outside of the EU) will contain RoHS substances and with this exemption will enter the EU market in the future, but also, a similar quantity of parts recovered from medical devices placed on the EU market before 21 July 2014 will also leave the EU. Overall, there will be no net change in the amounts of these substances present within the EU as the amounts entering will be similar to the amounts leaving.

6. Name of material/component: An illustrative non-exhaustive list includes:
   - Lead in solders and solderable coatings of components;
   - Lead in ceramic capacitors;
   - Lead in pigments (mainly used in paints and polymers);
   - Lead in copper and aluminium alloys at concentrations higher than permitted by exemptions 6c and 6b of Annex III, e.g. used for bearings, to make gears for gearboxes, in fasteners, etc.;
   - Lead in electroplated coatings used on plugs and sockets;
   - Lead stabilisers in PVC cables and other PVC parts;
   - Cadmium in pigments used in applications that are exempt from the REACH Regulation;
   - Cadmium in brazed parts such as to attach pipes used for cooling equipment;
   - Hexavalent chromium in passivation coatings on metals;
   - Hexavalent chromium in pigments, e.g. used in labels, etc.;
   - Deca-BDEs in plastic parts and in coatings;
   - RoHS substances in applications that had been previously exempted under RoHS Annex III and IV;

7. Environmental Assessment: Yes, provided in section 6.

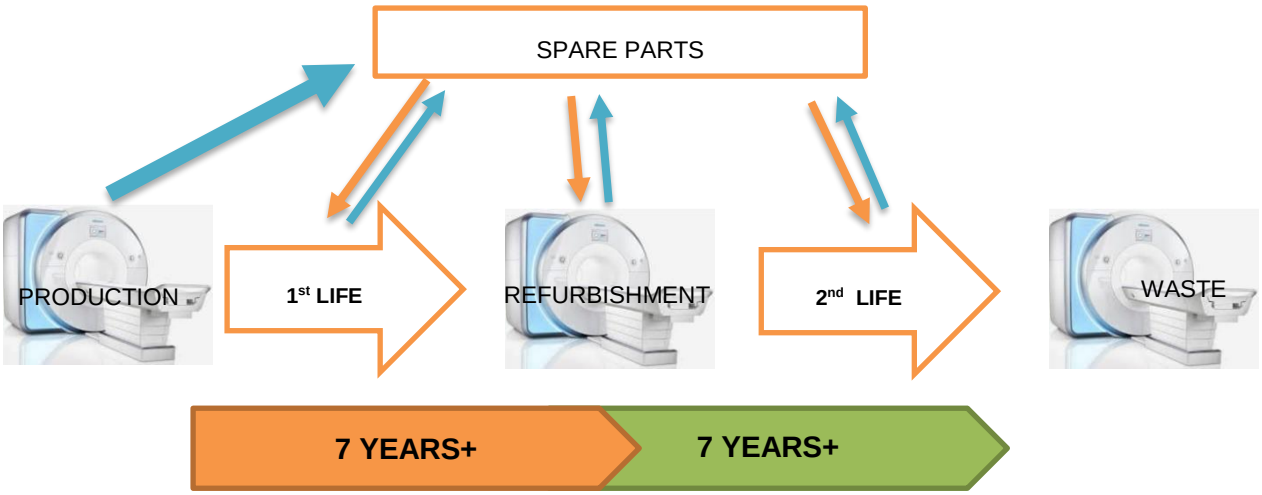
   LCA: ☒ Yes
   ☐ No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is

the function of this material or component?

Before describing the parts that are recovered for reuse, it is necessary to explain why this exemption is required for another 7 years period with the same text that was already adopted in 2015.

As already explained in the original submission of exemption 31a, recovered spare parts may be used for a period of at least as long as twice the life of a medical imaging device (some parts are reused more than once). Spare parts need to be available to repair the equipment during its first life (7 years on average, but some are used for much longer), and then during its second life after refurbishment (5 to 7 years on average). As more and more devices are able to be upgraded, the life-time of medical devices is currently significantly increasing. Some parts are reused many times, such as X-ray tube housings, which can have technical lifetimes of up to 25 years. The number of non-compliant spare parts available to be used will decrease over time as new RoHS compliant spare parts become available from post-2014 medical devices (and post 2016 IVD MDs). For example, a non-compliant medical device placed on the market in 2013, may be refurbished after 7 years (so in 2020) and then again in 2027 or even later. For this reason exemption 31 a needs to be renewed.



Many types of part are recovered from used medical devices and then these parts are reused for the repair, maintenance, servicing or refurbishment of other medical devices. The medical imaging sector is a frontrunner in the implementation of a circular economy business model. The RoHS Directive allows non-compliant spare parts to be used to repair medical devices that were placed on the EU market before 22nd July 2014. However other recovered parts cannot be used after 2014 if they contain RoHS-restricted substances. Exemption 31a, published in 2016 (amending previous exemption 31, published in 2013) was carefully crafted to allow recovered spare parts to be used without unwanted limitations (the problem with exemption 31), recognizing the environmental and social benefit of reuse. Exemption 31a needs to be renewed for

another 7 years period, with the same wording, to allow recovered spare parts to be used to repair and service installed products until the end of their service life as well as to refurbish used medical devices.

Without this exemption the following scenarios will occur.

Table 1. Effect of source of equipment and parts on whether they can be reused without exemption 31a

Source of recovered part	**Identity of medical device in which the recovered part is used for repair/maintenance**	**RoHS compliance status of recovered part without exemption 31a**	**Could this part be used in a medical device placed on the EU market after exemption 31a expires?**
From a medical device regardless of whether it was originally sold before July 2014, which may contain RoHS-restricted substances	Medical device placed on the EU market before 21 July 2014 (yes 6 substances, yes 4 phthalates)	May contain RoHS substances	Yes, thanks to RoHS article 4.4
	Medical device placed on the EU market between July 2014 and July 2021 (original 6 substances restricted, 4 phthalates not yet banned)	May contain RoHS substances	Yes, permitted by actual exemption 31a and Article 4.4(f)
	Medical device placed on the EU market after 21 July 2021 (no 6 substances, no 4 phthalates)	May contain RoHS substances	**No, cannot be used unless exemption 31a is renewed with the same original wording**
From a medical device regardless of where it was originally sold between July 2014 and July 2021 which may contain RoHS substances due to an expired exemption	Medical device placed on the EU market before 21 July 2014 (yes 6 substances, yes 4 phthalates)	May still contain original 6 RoHS substances not covered anymore by existing exemptions + phthalates	Yes, due to article 4.4
	Medical device placed on the EU market between July 2014 and July 2021 (contains no original 6 restricted substances except	May still contain original 6 RoHS substances but not covered anymore	Yes, due to article 4.4(f)

	covered by exemptions, may contain the 4 phthalates)	by existing exemptions + phthalates	
	Medical device placed on the EU market after 21 July 2021 (no 6 substances and no 4 phthalates unless covered by exemption)	May still contain original 6 RoHS substances not covered anymore by existing exemptions + phthalates	**No, cannot be used unless exemption 31a is renewed with the same original wording**

The table above includes the situation where a recovered part contains a RoHS substance used in an exempt application when it was originally installed in a medical device, but this exemption has since expired. This will be an issue for refurbishment of non-EU medical devices if these are placed on the EU market (i.e. sold as refurbished equipment to an EU hospital) after the exemption has expired. Article 4.4f of RoHS allows the use of spare parts in "EEE which benefited from an exemption and which was placed on the market before that exemption expired". This does not allow these parts in medical devices that were originally sold outside of the EU and then imported as refurbished equipment after the exemption expires. COCIR believe that this will mainly be an issue with Annex IV exemptions that expired before 2021

Determining if RoHS restricted substances are present in recovered parts

Without this exemption being renewed, after July 2021, most recovered parts could not be used as most will probably contain RoHS substances if manufactured before 2014, or they may contain RoHS substances not covered anymore by an expired exemption, if manufactured after 2014. The only solution for the OEM, would be to analyse all parts to determine if they contain restricted substances. For the same reasons explained in the original request of exemption 31a, some RoHS substance uses can be determined by analysis using non-destructive X-ray Fluorescence (XRF) screening analysis. However, this is not always definitive and can give incorrect results. It is also unsuitable for hexavalent chromium and PBDEs which can be analysed only by destructive analysis methods. Also, larger or more complex parts need to be opened to analyse internal materials and this is usually destructive. It is therefore usually impossible to determine compliance without destroying the part.

Importance of the current wording

Exemption 31a, published in 12/02/2016[1], recognized the principle that the

environmental benefits of reusing a part are always greater than manufacturing a new part and destroying the old one. It is a basic principle of the EU Circular Economy, reconfirmed in the Waste Framework Directive in 2018, that reuse and life extension are always far better options than waste recycling and manufacturing of replacement new products.

Exemption 31a, allows the use of recovered spare parts from medical devices to be reused for the repair, refurbishment , servicing or maintenance operations regardless of when and where the medical devices from which the parts originated was previously placed on the market. This is very important otherwise the most recovered spare parts could not be used as only about one third of new medical devices are sold in the EU. This means that two thirds of recovered parts could not be used to refurbish, repair, service or maintain medical devices that have been placed on the EU market after 21 July 2021 without this exemption maintaining its exact wording. In fact the situation will be even worse because it is usually not possible to reliably determine whether a spare part had been removed from a medical device originally sold in the EU before 21st July 2014 or it is from equipment that had previously been sold to a user outside of the EU. To ensure full compliance, without this exemption, with RoHS, it would be necessary for manufacturers to halt any refurbishment operation (or to sell refurbished equipment outside of the EU only) and to stop using all recovered spare part for refurbishment, repair, servicing or maintenance in the EU to avoid the risk of unintentional non-compliance. This would have the following negative impacts:

- No availability of refurbished medical devices in the EU. This will prevent hospitals from obtaining refurbished equipment. If these hospitals cannot afford new equipment (which can be up to double the price) but refurbished models of a few years old would provide the diagnostic capability and treatment that they need, this would have a negative impact on healthcare. This is due to:
    - No availability of the required equipment means that patients have to be diagnosed and treated using less effective methods with potentially inferior outcomes and longer treatment/ waiting times. Patients may alternatively have to travel further to different hospitals, which is an issue for elderly and very ill patients
    - Having to use older equipment for longer can have two problems. Older models may have inferior diagnostic capability and the reliability tends to deteriorate as equipment becomes older so as maintenance is required more frequently this will impact the diagnostic.
- At least one third of global sales of refurbished medical devices are sold in the EU. If this market was no longer available, this equipment would become waste, at least until other markets outside of the EU can absorb the surplus, which would take many years. Therefore increasing the quantity of waste
- It would be the end of the circular economy business model in the EU for a front

running sector.

- The costs to repair and also to differentiate conforming from non-conforming parts and differentiate spare parts originating from EU from non-EU equipment (if this were to be technically and logistically possible, which is very unlikely), will in most cases be more costly than just manufacturing a new part. Without this renewed exemption, most manufacturers would be forced to significantly decrease their repair and refurbishment business in the EU which would negatively affect EU hospitals.

Types of recovered parts that are reused

The original exemption request[2] submitted by COCIR in 2011 explained that medical device manufacturers recover many types of part from used equipment for reuse. One example manufacturer is collecting and reusing about 3,500 different parts. The most commonly recovered and reused types of part are:

- MRI coils
- Printed circuit boards from many different types of equipment
- Detectors and components of detectors (e.g. radiation detectors)
- X-ray tubes

For example, X-ray imaging equipment consists of many sub-assemblies including those used for patient support, holding and moving the X-ray tube and the X-ray detector into the required positions and the, the X-ray tube assembly and detector assembly. X-ray imaging systems typically have very long lives often exceeding 25 years but the X-ray tubes have shorter lives, which can be as short as 6 months or as long as 15 years depending on the frequency and intensity of use. Some types of X-ray tube assembly are returned on average every two years whereas other types are returned on average after longer periods. The average period for all tubes is estimated by COCIR to be about 5 years.

X-ray tube assemblies have to be periodically replaced because of bearing wear or erosion of the anode and so the X-ray tubes with their housing assemblies are returned to the manufacturer who re-uses as many of the constituent parts as possible including the housings, to make new X-ray tube assemblies. New assemblies built from reused parts are used as replacements for existing X-ray systems and may also be used to construct new systems. Typically, the parts from an X-ray assembly housing can be reused at least five times (one manufacturer's average is reuse three times) and as each has an average lifetime of 5 years, they could be used at least 25 years before recycling of materials. This period would be very much reduced if this exemption were not renewed.

One of the largest parts of the assembly that is reused is the external housing. This is constructed from aluminium alloys or sometimes brass, some steel parts, lead sheet

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2 http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_VI/Request_2/COCIR_-_Exemption_request2_-_X_ray_and_other_parts_reuse.pdf

as radiation shielding and a few other materials. The aluminium alloys and the brass in some cases are also alloyed with lead which acts as radiation shielding.

The X-ray tube assembly housing has a number of small inserts which have in the past been, treated with chromate passivation coatings to prevent corrosion and so the coatings contain a very small quantity of hexavalent chromium. Chromate passivation treatment has been replaced by all medical device manufacturers, so only recovered parts from equipment placed on the market before July 2014 will contain these coatings, but these parts could potentially be reused for 25 years until 2039 if allowed by exemption 31a.

Housings that contain hexavalent chromium will be reused many times unless they are damaged or if this is prevented by the RoHS directive due to the presence of a restricted material that has no exemption. Allowing the reuse of housings and other recovered, reusable parts would have a significantly smaller environmental and health impact than preventing their reuse which would mean making new parts to replace them.

All other parts of X-ray tube assembly are reused if possible but many do not contain RoHS restricted substances. Some designs contain printed circuit boards some of which were made with lead solders before July 2014. Many contain electric motors and cables where older pre-2014 parts may contain lead stabilisers in the PVC insulation although lead solders and lead stabilisers have not been used to make new parts since medical devices entered scope of RoHS.

Plastic components and mouldings may have been made using PBDE flame retardants before July 2014. Now in 2019, it is impossible to determine from the plastic manufacturer which flame retardant was used at least five years ago. The only way to determine if the plastic contains PBDE is by destructive chemical analysis and this would make the part unusable, so would be pointless.

Many other parts are recovered from medical devices. These include MRI coils, PCBs from many types of equipment, ultrasound transducers, monitors, grids, collimators, etc. Some of these will contain small amounts of RoHS substances which were legally used when the parts were first used.

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

The RoHS-regulated substances used in the EEE as described in Section 4 (A)1 were originally used for technical reasons as outlined below, however the basis of this exemption is not justified on this basis, rather the overall health and environmental impact

The function of each use of each RoHS-regulated substances include:

- Lead in solders and in terminal coatings for making electrical connections with

high reliability or magnetic requirements

- Lead compounds as PVC stabilisers
- Lead in ceramics of ceramic capacitors that was permitted by exemption 7cIII (expired Jan 2013 so may occur in medical devices made before 2013)
- Hexavalent chromium compounds in passivation coatings for its corrosion properties
- Deca-BDE flame retardants used in various polymers

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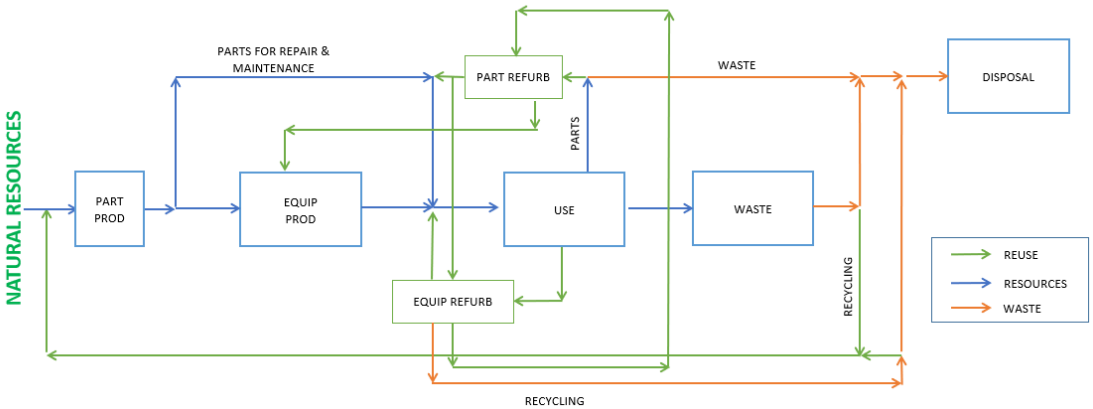
5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

Yes. Medical equipment manufacturers make great effort to collect used equipment that they can refurbish and also parts such as used X-ray tubes that they can refurbish for reuse.

Medical equipment manufacturers make great effort to collect their own brand of used equipment from their clients and occasionally from brokers when their equipment is not sold back to them directly (there is no obligation for hospitals to sell it back to the OEM). Manufacturers do no collect medical devices made by other manufactures. The equipment that cannot be refurbished are treated as waste according to the WEEE Directive, the others are refurbished. Parts recovered from devices during refurbishment (or repair/maintenance) are used to repair, maintain, service or refurbish other equipment, so that parts remain within a “closed-loop”.

The chart below shows the flow of equipment and parts of each manufacturer within the medical imaging sector**Error! Bookmark not defined.**.



An example of a frequently reused part is recovered X-ray tubes. These are supplied only to businesses and their return to the original manufacturer is guaranteed by

contracts agreed when the new imaging equipment is supplied. Typically, the contract will define a payment to the user of the imaging equipment when they return the used X-ray tube assembly to the original manufacturer. This payment can be as much as €1,000 and so ensures a very high return rate; in fact it would be surprising if used assemblies were not returned. All manufacturers in the EU use these arrangements and pay for the return of their X-ray tube assemblies because they contain valuable parts. Typically ~95% of assemblies are returned to the original manufacturer. The fate of the rest is unclear but some at least are collected and the parts reused by different organisations. The number of used assemblies going to landfill is believed to be negligible. As all reused parts are manufactured, recovered and reused by the original manufacturer, this is a "closed-loop".

An additional reason why refurbishment must be closed loop is from obligations of the Medical Devices legislation. Medical device manufacturers cannot reuse refurbished components unless the reprocessing method has been approved. Usually, only medical device manufacturers apply for approval for reprocessing parts that are used in their own products. This mandatory requirement is required to ensure that only approved parts are used in the process (new or used), to ensure safety and performance of medical devices.

2) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling

☒ Article is collected and completely refurbished for reuse – It should be noted that this refers to the recovered parts only – these are completely refurbished for reuse and this does not refer to medical devices, for which the terms "completely refurbished" or "fully refurbished" have legally binding meanings in the Medical Devices Regulation.

☐ Article is collected and dismantled:

- ☐ The following parts are refurbished for use as spare parts: _____
- ☐ The following parts are subsequently recycled: _____

☐ Article cannot be recycled and is therefore:

- ☐ Sent for energy return
- ☐ Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

☒ In articles which are refurbished Not known as the RoHS substances were used in parts that were made in the past and it is not possible to non-destructively obtain information on substances in these parts

☐ In articles which are recycled _____

☐ In articles which are sent for energy return _____

☐ In articles which are landfilled _____

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

The medical sector reuses many types of parts and the overall impacts of the two following scenarios are compared here:

1. If this exemption were to be renewed
2. If this exemption is not renewed

These two scenarios are compared using three Life Cycle assessments (LCAs). These are an LCA given at the end of this questionnaire in Annex I for the reuse of X-ray tube housings and two comparative LCAs (below) for a) equipment refurbishment, and b) reuse of printed circuit boards. These can be compared quantitatively, but there are also qualitative human health impacts that are also described below in life cycle terms.

Comparison of impacts from equipment refurbishment versus new parts manufacture

The two scenarios of 1) renewal of this exemption and 2) exemption expiry are compared for all recovered reused parts by the life cycle assessment below. The chart below shows the impacts that will occur with and without the exemption.

Table 2. Comparison of impacts from scenarios of exemption 31a being renewed compared to exemption 31a expiry without renewal

With exemption renewal	Without exemption
100% of recovered parts can potentially be reused	Most of the recovered spare parts cannot be used as the presence of RoHS restricted substances or the origins of the device from which they were recovered are often not known.
Fewer new components will be manufactured and more medical devices will be refurbished.	Refurbishment of medical devices will have to use newly manufactured parts. However, this may not be possible for older parts that have been discontinued. Therefore fewer medical devices will be refurbished for reuse in the EU. Making small numbers of specially made new parts will be considerably more expensive than

	use of recovered parts and this will make refurbishment costs too high to be viable as an alternative to new equipment.
Less waste as 100% of undamaged, recovered parts can potentially be reused.	Recovered parts will become waste if they cannot be used outside of the EU as they cannot be used in the EU.
All refurbished equipment can be sold in the EU or elsewhere.	Unless new parts can be made, refurbished equipment will not be available in the EU, which will impact on EU hospitals.
Greater availability of spare parts for repair, servicing and maintenance which will ensure shorter downtime of essential medical devices for EU citizens and avoid delays in urgent medical treatment	Much lower availability of spare parts for repair of EU medical devices ensuring longer downtime of essential medical devices and delays in provision of urgent medical treatment to EU citizens. When medical devices are out of warranty, new spare parts may not be available (if production is discontinued) and so it could take up to 8 months to manufacture replacement parts, if this is feasible)

The justification for this exemption is that the overall health, safety and environmental impact without this exemption is more negative than the overall health, safety and environmental impact with this exemption. Some of these impacts can be determined quantitatively, but others only qualitatively. Qualitative impacts are considered first as follows.

Safety impacts include:

- Hospitals that cannot afford new equipment are often able to buy refurbished equipment that is considerably newer than the old equipment that it will replace. The reliability and diagnostic and treatment performance is usually proportional to the age of the equipment. If an old medical device develops a fault, the resultant non-availability due to either the medical device age or availability of reused parts, can pose a serious safety risk to patients if they cannot be treated and if delays occur. As a worst case, delays can lead to death, but more often the patient suffers for longer and their illness worsen.
- The lower availability of parts for repair and maintenance on a global scale will cause longer downtimes for healthcare providers, especially if new parts have to be custom made, with a negative health and safety impact on patients.

Environmental impacts include:

- The manufacture of replacement parts will cause an environmental impact due to the emissions of global warming gases and hazardous substances to air, water and land. This will also consume more resources and produce more

wastes. Refurbishment uses very small quantities of substances and energy in comparison and usually generates no waste.

- The relative impacts of RoHS restricted substances compared with alternative substances on the environment should be considered. Substitutes are rarely benign and their impacts in terms of harmful emissions (e.g. from materials production and energy generation), etc. are captured by Life Cycle Assessments (see below).

Health impact

- The relative impacts of RoHS restricted substances compared with alternative substances on the health of workers, users and the public should be considered. Substitutes are rarely benign and their impacts in terms of harmful emissions (e.g. from materials production and energy generation), etc. are captured by quantitative Life Cycle Assessments, which are described below.
- Health impact of manufacture of new replacement parts will cause larger emissions of global warming gases and hazardous substances, consume more resources and produce more wastes than refurbishment of parts. Refurbishment of recovered parts and equipment uses very small quantities of substances and energy in comparison with new parts and usually generates no waste.

Hospitals in all EU Member States have limited funds for new equipment and frequently purchase refurbished medical devices due to their lower price and ability to provide a capability that is sufficient for the hospital's needs. Today we already see that the demand for refurbished equipment exceeds the numbers that are available. As a result, the ability to buy refurbished medical devices reduces the average age of the hospital's medical equipment, because a refurbished device usually replaces an older device. The money saved may possibly allow another medical device to also be obtained that may replace another older device. If refurbished medical devices are not available, the hospital would eventually have to buy a new device, but this is likely to be delayed until sufficient funds become available, which could be several years or more.

During the period between when a refurbished device which relies on this exemption could be purchased and the date when a new device was affordable, patients will experience the following:

a) There may be no medical device available at the nearest hospital and so they may need to travel a long distance (this would be case when a hospital buys its first MRI, CT, etc. although this would be less common today). Travelling longer distances is difficult for people with ill health or elderly or patients with reduced mobility. As this also increases the demand at other hospitals, which in turn can result in delays to treatment due to increased waiting lists for treatment.

b) Older equipment tends to be less reliable than newer devices due to wear and tear. While the device is not functioning and awaiting repair, patients cannot be treated. Not being able to treat patients can have serious implications and as a worst case lead to death, but at best longer recovery times. As an illustrative

example, stroke victims can be effectively treated if the hospital staff can quickly determine if the cause is a blocked artery or a burst artery. Treatments for each are different and it dangerous to use the wrong treatment. Stroke victims are diagnosed by either CT or MRI and this must be carried out within a few hours of the stroke for the patient to have any chance of a full recovery. If the CT or MRI is not available then the patient's likelihood of recovery are greatly reduced.

c) If recovered and refurbished spare parts are not available to repair medical devices, new parts have to be made or a higher level component (i.e. a whole module rather than a small PCB used inside the module) needs to be replaced. The resultant delay can have serious negative implications for patients.

d) Older equipment may not have the same performance as newer refurbished equipment. For example, magnet power of MRI has increased in the last decades and increased magnet power gives superior image quality that could allow medical staff to detect tumours earlier or see smaller blood clots, etc. Earlier diagnosis results in improved likelihood of recovery and gives faster recovery. It can also allow simpler medical procedures to be used such as keyhole surgery rather than more invasive treatments when for example, tumours become larger. Earlier diagnosis therefore can shorten time in hospital, give quicker recovery and give cost savings to hospitals.

It is not possible to quantify the benefit of a hospital being able to buy refurbished medical devices or repair equipment more quickly, as so many unquantified variables affect patients' recovery and treatment costs, but as described above, qualitatively, the ability to reuse recovered parts has clear health, safety and environmental benefits.

Parts collected from used equipment have already been manufactured and so any health or environmental impacts have already occurred. If the parts cannot be reused, they will reach end of life prematurely and new parts will have to be manufactured as replacements and this will have a negative environmental and health impact. Manufacture of new parts will consume energy, use natural resources and create emissions and waste. Generation of the energy used for manufacturing is mainly using fossil fuels globally and this creates harmful emissions and wastes due to coal and oil combustion for electricity generation as well as in material production furnaces. Coal and oil are still the dominant energy source in the countries (e.g. USA, China, India) where most raw materials and components are manufactured that are used in medical devices. Coal and oil contain naturally occurring lead, cadmium, arsenic and mercury and these are emitted during combustion. Some is emitted to air where it can travel long distances before being deposited onto land or into water supplies. The rest is scrubbed from emissions to form solid hazardous waste that needs to be carefully disposed of in well-managed landfill sites to avoid the toxic substances from being leached out into water supplies.

Since 2015, Europe has accepted the concept that reuse is always the best form of

materials management. Reuse is number one in the waste hierarchy and so there is no need to prove the very basic concept of circular economy[3].

As parts containing RoHS substances will stay in the loop for longer, they will also be recycled at a later point of time, and therefore benefitting from better and newer technologies for recycling. Also fewer new parts need to be produced or are manufactured at a later point of time, and therefore also benefitting from the ongoing increase of environmental efficiency (usually this is 5-10% per year).

LCA for MRI and X-ray system refurbishment versus new parts manufacture A full life cycle assessment has been produced by Tsinghua University that compares building new medical devices compared to refurbishment considering X-ray systems, MRI, PET and CT[4]. This publication reports that 95% of MRI can be refurbished, 85% of CT and 65% of X-ray systems. The global energy saving from refurbishment of these three types of medical devices gives an annual life cycle energy saving of 211 MWh including energy saved by not making new parts when recovered used parts can be used. Figure 7 of this publication shows the LCA results for 18 environmental and human life cycle impacts. **All** impacts from refurbishing systems are significantly smaller than for building new systems. Three illustrative impact examples for MRI and for X-ray systems are shown below:

Table 3. Examples results of life cycle assessment comparison of new and refurbished MRI and X-ray systems.

Impact	**Size of impact of refurbished system compared with a new system (which is 100%)**	
	MRI	**X-ray system**
Climate change	27%	3%
Human toxicity	32%	6%
Terrestrial ecotoxicity	28%	5%

Manufacture of new replacement parts will consume energy and materials, whereas already existing recovered parts will consume very little or no energy and materials to be reusable.

LCA for printed circuit board parts reuse versus new parts manufacture

[3] European Parliament website on circular economy: http://www.europarl.europa.eu/news/en/headlines/economy/20151201STO05603/circular-economy-definition-importance-and-benefits

[4] Energy savings and environmental impacts of refurbishing medical devices approaching end-of-life: A case study of MRI and X-Ray scanners, Gabriel I Zlamparet et.al. Unpublished work that can be provided to the European Commission

LCAs have been published for some of the materials that are used in replacement parts. For example, printed circuit board (PCB) life cycle impacts have been calculated by VHK for the European Commission which is used for eco-design preparatory studies[5]. Impacts for several different types of PCB have been calculated and example impacts from the manufacture life cycle phase for 1kg are shown below. Note that the data shows that most of the life cycle impact is incurred in the production phase for most impacts:

Table 4. Selected whole life cycle environmental and health impact data from VHK ecodesign study

Type of electronics	Global warming impact	Heavy metals emissions to air	Waste, hazardous/ incinerated and non-haz landfill
PWB 1/2 layer 3.75kg/m2	20 kg CO2 equivalent	37 mg Ni equivalent	1.74 kg haz waste plus 2.7kg non-hazardous waste landfilled
PWB 6 layer 4.5 kg/m2	25 kg CO2 equivalent	70 mg Ni equivalent	1.9 kg haz waste plus 4.2kg non-hazardous waste landfilled
Surface mount devices	176 kg CO2 equivalent	423 mg Ni equivalent	135 grams haz waste plus 2.9 kg non-hazardous waste landfilled
IC's avg., 5% Si, Au	514 kg CO2 equivalent	448 mg Ni equivalent	241 grams haz waste plus 8.9 kg non-hazardous waste landfilled
Controller board	125	427	97 grams haz waste plus 2.1 kg non-hazardous waste landfilled

The proportion of recovered used parts that can be reused for refurbishment, repair, maintenance and servicing varies depending on the type of part. COCIR estimated in 2011 when requesting the exemption that was granted as 31a, that 85% of recovered

[5] Methodology for Ecodesign of Energy-related Products, MEErP 2011, Prepared for the European Commission, DG Enterprise and Industry, Unit B1 Sustainable Industrial Policy, contract SI2.581529, R. Kemna.

parts can be reused. Zlamparet et al[4] report that 50% of cables can be reused but some parts such as patient table covers are much less often reusable (only 10%).

COCIR has estimated that about 2,200 tonnes of parts and 1,000 tonnes of equipment (total 3,200 tonnes) are refurbished and then reused in the EU annually[6]. Many of these parts such as X-ray tube assemblies and PCBs have long lifetimes and so may be reused more than once, although some parts will be found to be damaged and so have to be replaced by a new part. Reuse of recovered parts will continue into the foreseeable future but as old parts reach end of life and newer recovered parts that were made since July 2014 that do not contain RoHS restricted substances become available for reuse, the total quantity of the RoHS substances in circulation will gradually decrease to zero. This means that with this exemption, about 3,200 tonnes of medical equipment and collected used parts can be refurbished and could be reused in the EU annually, but the total quantity of RoHS restricted substances present in these parts is gradually decreasing annually. At the end of July 2014, there were noparts recovered that were manufactured at dates after medical devices were in scope of RoHS, but this some post-July 2014 parts will be recovered, probably by 2020 and the proportion of parts that are post-July 2014 will slowly increase and will eventually reach 100%. Without this exemption, it will be impossible to reuse recovered parts in EU medical devices because of the implications described in this document.

The impact of not granting this exemption would be a need for an additional 2,200 tonnes of new parts to be made each year, with its associated impacts mainly for repairs, maintenance and servicing. In theory, post-2014 parts will eventually become available, but identifying them is not straightforward and so it would be many years before these can be used if this exemption is not renewed.

If we assume hypothetically that the PCBs that are reused consist of 30% 1 or 2 layer boards, 40% is surface mount devices and 30% ICs, using the VHK ecodesign impact data, the impacts will include the following:

Table 5. Estimated EU impacts from replacement printed circuit boards used for repair, maintenance and servicing of medical devices in the EU that would arise without this exemption.

Impact	EU total
Global warming impact	511,932 kg CO_2 eq
Heavy metals emissions to air	743 g Ni eq
Waste, hazardous/ incinerated	1,439 kg
Non-hazardous waste landfilled	10,301 kg

In addition, there are other negative impacts from new parts manufacture such as particulate and POPs emissions, emissions to water and energy and resource

[6] COCIR Self Regulatory Initiative for medical imaging equipment, status report for 2016, http://www.cocir.org/fileadmin/6_Initiatives_SRI/SRI_Status_Report/COCIR_SRI_Status_Report_2016_final_12092017.pdf

consumption that would not occur if this exemption is renewed. There are no negative impacts from the continued use of the RoHS substances that are already present in manufactured parts as the only effect of granting this exemption is to delay when they eventually reach end of life. These parts will eventually reach end of life and be recycled irrespective of whether this exemption is granted.

An additional comparative LCA for X-ray tubes is given in Annex I

Overall Life Cycle Assessment

The difference between the overall safety, human and environmental impacts with and without this exemption described above and in Annex I are significant and are summarised below:

- The results of an LCA study[4] comparing new and refurbished systems shows that the size of 18 environmental and human impacts is considerably smaller for refurbishment compared to building new equipment;
- Reuse of recovered parts for maintenance, repair and servicing gives significant reductions in many environmental and human impacts that are demonstrated using the VHK ecodesign life cycle assessment tool. Refurbishment has a smaller impact than manufacture of new replacement parts for all human health and environmental impacts;
- The LCA for X-ray tube housings in the Annex compares the quantities of materials and energy consumed for two scenarios; with this exemption renewed and without this exemption. The impacts with this exemption are clearly smaller.
- Repairs may be delayed if refurbished recovered parts cannot be used. This will cause delays in providing medical treatment until a replacement new part can be sourced, which could take many months. Delays in medical treatment can have serious negative health impacts on EU citizens;
- Many EU hospitals are able to buy the more complex types of medical device, such as MRI and CT, because refurbished equipment is available at up to 50% discount. This equipment often provides the medical diagnostic and treatment capability that the hospitals require. Without this exemption, the availability of such equipment would be very much diminished so that EU hospitals are unable to obtain this equipment with the resultant negative health impacts on patients. If they were forced to and able to buy new equipment at the much higher cost, this could prevent them from buying other medical equipment as their budgets are always limited and the non-availability of this equipment would have a negative health impact on patients.

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

Not applicable to this renewal request as reused parts should be identical to new parts

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7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

Not applicable as reuse has a less negative overall impact on health, safety and the environment than disposal and replacement. This exemption will no longer be needed when all parts that are recovered from used medical devices are made July 2014 and after this date. Some parts have lifetimes of at least 25 years when reused several times.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

In the future, the number of pre-2014 parts that contain RoHS restricted substances will gradually decrease as they are reused and eventually reach end of life in a state where they are no longer suitable for reuse. Although the quantity of reused parts will continue at about the same level or slightly increase into the foreseeable future, the quantities of RoHS substances present (except where exempt) will gradually decrease, eventually to zero.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

☒ SVHC – Deca-BDE and lead and cadmium metals

☒ Candidate list – includes deca-BDE and lead and cadmium metals

☒ Proposal inclusion Annex XIV – deca-BDE, but this would have no impact as only previously made articles are reused in the EU.

☐ Annex XIV

☐ Restriction

☒ Annex XVII –Penta- and octa-BDE have been restricted by REACH for many years, but Deca-BDE has been restricted by REACH in articles placed on the market since 2 March 2019. Penta-

BDE and octa-BDE were restricted in 2004 by REACH so should no longer occur in medical devices that are refurbished or parts that are recovered (those that contain flame retarded plastics are usually no more than 7 years old). Deca-BDE may occur but only in parts from medical devices made before July 2014 when medical devices entered scope of the RoHS Directive. However the REACH Regulation item 67 excludes medical devices that are in scope of RoHS (as per condition 4d).

Cadmium has specific restriction but with exemptions. These restrictions have been in force for over 40 years and so no medical devices that are refurbished or parts that are recovered will contain cadmium in restricted forms. Note that although cadmium is restricted in braze alloys, this restriction does not cover articles that have already been brazed or are made by brazing outside of the EU.

The only REACH restriction of hexavalent chromium is applicable only to cement and so this is not applicable

☐ Registry of intentions

☐ Registration – not relevant as only existing, previously made articles require this exemption. However, lead and cadmium are registered.

2) Provide REACH-relevant information received through the supply chain.

Name of document: _____

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

   ☒ Yes. Consequences? Overall more negative health, safety and environmental impact as explained above

   ☐ No. Justification: _____

2. Can the substance named under 4.(A)1 be substituted?

   ☐ Yes.

   ☐ Design changes:

   ☐ Other materials:

   ☐ Other substance:

   ☒ No. Not without considerable negative health, safety and environmental impacts

   Justification: See explanation in section 6 above

3. Give details on the reliability of substitutes (technical data + information): Not applicable
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: More negative, see section 6 above
   2) Health impacts: More negative, see section 6 above

3) Consumer safety impacts: Likely to have a negative impact on EU patients' health if exemption 31a is not renewed, but the equipment should have no safety implications on consumers

⇨ Do impacts of substitution outweigh benefits thereof? Yes, see section 6

Please provide third-party verified assessment on this: Attached as separate document from RINA Consulting (previously ERA)

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Some parts are now obsolete and so obtaining substitute new parts will be difficult

b) Have you encountered problems with the availability? Describe: No, but replacement parts may be more costly and cause delays, as explained above

c) Do you consider the price of the substitute to be a problem for the availability?

☐ Yes ☒ No Without an exemption the costs to hospitals for repair and refurbishment will increase as equipment manufacturers will need to make and buy more new parts. Higher prices of new parts or new equipment will negatively affect EU hospitals if they have to pay higher prices, although does not directly affect availability.

d) What conditions need to be fulfilled to ensure the availability? This exemption needs to be renewed

(D) Socio-economic impact of substitution:

⇨ What kind of economic effects do you consider related to substitution?

☒ Increase in direct production costs – without this exemption, as more new parts will need to be made, there would be an increase in costs that would have to be passed on to hospitals and clinics in the EU

☐ Increase in fixed costs

☐ Increase in overhead

☒ Possible social impacts within the EU – as explained in answer to Q6, there are socio-economic impacts. Also, if refurbished parts are not available in the EU, the higher cost of new parts would be passed on to hospitals and clinics. As all EU hospitals and clinics have limited budgets, this will impact on healthcare expenditure elsewhere so negatively affect healthcare of EU citizens

☐ Possible social impacts external to the EU – none as recovered refurbished parts can be used even if this exemption were to expire

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement: It is not possible to quantify socio-economic impacts because the health of EU citizens is affected by a large number of variables such as education, quality of food, affluence,

advances in medicines and treatments, etc. The issues described in the documents will clearly have socio-economic impacts but the extent cannot be quantified.

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

_____

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10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:

_____

Annex I

LCA for X-ray tube assemblies

An illustrative example of X-ray tube assemblies is provided here in which the overall health and environmental benefits can be demonstrated by comparison of the two alternative scenarios.

1. With exemption allowing reuse, or;
2. Without exemption so that parts become waste and have to be replaced.

The calculations below are until 2029 which is 25 years after medical devices entered scope of RoHS. 25 years is the longest likely period for use and reuse of X-ray tube housings, but some other parts of the assemblies may have longer or shorter lifetimes.

Table 6. Life cycle comparison of alternative options for chromate passivated aluminium housings

Life cycle phase	Scenario	
	1. With exemption	2. Without exemption
Production of materials and manufacture of parts	Parts already produced so minimal impact as new parts needed only to replace those that are damaged	New materials would have to be produced and parts constructed to replace all parts. Impact quantified below
Use phase	No evidence that passivation coatings pose a risk (discussed below)	Parts identical except for alternative passivation coating without hexavalent chromium used in new parts
End of life	Reused at least five times. Would eventually be recycled but this is delayed. Passivation coatings in waste equipment do not cause harm (see below)	Original parts would become waste sooner and this would consume energy to recycle metals. There will be more waste overall, the older unused parts and their replacements

Likelihood of harm from hexavalent chromium from passivation coatings

Hexavalent chromium compounds are classified as toxic and carcinogenic by inhalation. There is however no scientifically validated research data that shows that hexavalent chromium within processed passivation coatings on metal surfaces is a carcinogen or a cause of illness by skin contact, i.e. from handling coated parts. The main known risk from hexavalent chromium compounds is to workers who carry out passivation coating processes using aqueous solutions of chemicals that contain chromate salts when treating metal parts. Cases of cancer have occurred in the past before the risks were known and managed to today's standards. There is also a risk

to the public if waste coating solutions are not correctly treated before disposal and become present in drinking water supplies but this has occurred only very rarely.

There is no scientific evidence that handling metal parts that have chromate passivation coatings has any harmful effect despite large numbers of treated parts being frequently handled by many thousands of workers over many years. At end of life, processes that recycle metals such as melting will completely destroy hexavalent chromium by converting it into safer trivalent chromium or chromium metal. For example, if chromate passivated aluminium is melted, the coating, which has a complex composition that contains metal chromates, typically reacts as follows:

$$6Al + Al_2(Cr_2O_7)_3 = 4Al_2O_3 + 3Cr_2O_3$$

Cr_2O_3 is trivalent chromium oxide and aluminium will also react with Cr_2O_3 as follows:

$$2Al + Cr_2O_3 = Al_2O_3 + 2Cr$$

Al_2O_3 (aluminium oxide) and chromium metal (Cr) are much less hazardous than hexavalent chromium and both occur commonly in electrical equipment (e.g. aluminium oxide as anodised coatings and chromium metal in stainless steel).
It is clear that the only significant risk is during the production phase where aqueous solutions of chromate salts that were used for passivation were handled. Once parts have been made, there is no evidence of a health or environmental risk to users (e.g. by hospital workers) or to workers who handle coated parts when they are refurbished (they are not repassivated) or at end of life and so continued use of coated parts does not appear to cause harm.
The coating processes that used hexavalent chromium salt solutions were phased out by the medical sector before July 2014 and have been replaced by safer processes, which are now used for all new parts. In conclusion, there is no evidence that the continued use and reuse of X-ray tube housings having passivation coatings that contain small amounts of hexavalent chromium would harm users, workers, the public or the environment.

Life cycle environmental impact comparison for X-ray tube assemblies

It has been estimated by COCIR that parts from about 16,000 X-ray tube assemblies are reused in the EU annually to construct new assemblies that are used in both new equipment and as replacements for existing equipment.
Re-use of these parts consumes very little energy or raw materials and no waste arises from the procedure used to dismantle used assemblies and then assemble new assemblies using these parts. If these parts could not be reused, then new parts would first need to be fabricated for up to 160,000 assemblies over 10 years and this will consume much more energy and create more waste than if the parts could be reused, as shown below.

The amendment 2017/2012/EU allows X-ray tube assemblies that contain RoHS substances from medical devices placed on the EU market before 21st June 2014 to be reused in the EU, but not if the equipment was previously sold outside of the EU.
It is impractical to segregate the construction of RoHS compliant assemblies (from EU systems) from non-RoHS compliant X-ray tube assemblies (from non-EU

systems) as this would require separate parts storage, two separate production lines and systems to prevent mistakes by using the wrong parts. In practice, manufacturers would not be able to reuse recovered parts as they cannot guarantee 100% compliance. Without renewal of this exemption many parts from pre-2014 housings are very unlikely to be used as manufacturers will want to avoid producing non-compliant products as a result of using the wrong tube assembly or build an assembly with the wrong parts due to an error. Many manufacturers of electrical equipment have experienced severe problems trying to maintain separate lead-free and lead-solder production lines, mainly due to mistakes in parts segregation and so very few manufacturers now operate dual segregated production lines.

The quantities of energy consumed, the mass of raw materials used and waste arising varies depending on the design and type of X-ray assembly. Each manufacturer has their own ranges of designs which uses different combinations of materials as well as size (and weight) of parts. Therefore the environmental benefits from reuse for each model are different.
Two medical equipment manufacturers have estimated the environmental benefits from reuse of either the housing only or all parts of the assembly as follows:

Table 7. Calculated benefits of reuse of aluminium housings

Manufacturer A – Reuse saving of assembly housing only (typical housing weight ~10kg Al)

Process / materials	Benefit/ saving	Assumptions
Energy consumption per housing	72 kWh	Data from supplier of housings includes energy for mining and refining metals
Energy per year	1.1 GWh	Assumes 16,000 reused in EU annually
Carbon dioxide emission saving	404 tonnes/year	0.35kg CO2/kWh generated

Table 8. Calculated benefit from reuse of parts from used X-ray tube assembly

Manufacturer B – reuse saving of all reusable parts for a typical design (typical housing weight ~10kg Al)

Process / materials	Saving per X-ray assembly	Saving for Annual EU reuse (16,000) per year	Assumptions
Manufacture of all raw materials used to make parts	764 kWh	12.2 GWh	Assumes virgin metals extracted and refined
Production of parts (melting, casting, machining, etc.)	902 kWh	14.4 GWh	Average value for all types of parts made
Recycling at end of life	-421 kWh	-6.7 GWh	Negative as this reduces the

			demand for virgin metals
Total energy saving	343 kWh	5.5 GWh	Takes into account the use of scrap
Total materials reused	29.2 kg	467 tonnes	Weight assuming 100% reused

The figures above from Manufacturer A are the energy saving by reuse of only the aluminium housing that contains a small amount of hexavalent chromium and the data from Manufacturer B is for the reuse of all parts of used X-ray tube assemblies, although only some of the parts will contain RoHS restricted substances.

Production of virgin aluminium from bauxite ore is very energy-intensive and typically consumes up to 20 times more energy than for recycling scrap aluminium. The ratio of virgin to scrap varies due to availability of scrap and the type of aluminium alloy used.

If materials reuse were not permitted, then the materials would be recycled and some material will be lost as recycling is not 100% efficient. These losses must be made up by production of more virgin metal. The recovery rate varies depending on composition and process but one manufacturer estimates that 94% is achievable but this would result in the loss of 28 tonnes (6% of 467 tonnes) of material (most to landfill) per year if no reuse were carried out.

Another way of estimating energy consumption for fabrication and recycling of the aluminium parts of the aluminium housings is from published data as follows:

Energy to produce new (virgin) aluminium = ~10 – 20 MWh/tonne (if scrap is not available[7]

- 16,000 housings at 10kg each = 160 tonnes = 1.6 – 3.2 GWh/year

End of life energy consumption:

- Recycling aluminium housing typical weight 10kg, energy to melt = 500kWh electricity/tonne so 50kWh each[8]. This is equivalent to ~125KWh of primary energy.
- 16,000 per year = 160 tonnes/year consuming = 200 MWh/year

Total = 1.6 to 3.2 GWh/year + 200 MWh/year = 1.8 to 3.4 GWh/year
Compared to virgin metal production and materials recycling, the reuse of recovered parts consumes negligible amounts of energy and no waste is generated.

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[7] From IEC BREF Non-ferrous metals http://eippcb.jrc.ec.europa.eu/reference/BREF/NFM/JRC107041_NFM_bref2017.pdf

[8] ENTR lot 4, from: https://www.eup-network.de/product-groups/preparatory-studies/completed/ See table 65.

The 10-year environmental impact of the manufacture of X-ray tube assembly housings is estimated below assuming the following:

- 16,000 are collected annually
- an average X-ray tube assembly life-time of 5 years,
- 85% of housings are reusable with an average of 10kg aluminium per assembly, resulting in 13,600 which are reused (85% of 16,000 is 13,600)
- 15% of used housings cannot be reused (15% of 16,000 is 2,400)
- Energy consumption saved per housing estimated by Manufacturer A is 72kWh.
- The calculated energy consumption value to manufacture each new aluminium housing from Manufacturer B is 307 kWh (a larger value as it is a larger housing).
- No housing will be refurbished after the exemption expires and is not renewed. A date of July 2021 has been assumed in Table 9 below.

The comparative life cycle assessment below compares the energy saved and materials reused by the two options: i) with an exemption and ii) with no exemption and assumes that each assembly has a life of 5 years and 15% of housings are too damaged to be reused.

Table 9. Comparison of impacts for X-ray tube housings with and without exemption 31a during period 2020 to 2029

Option	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
i) Reuse of all parts permitted										
Number of new needed	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400	2,400
Number reused	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600	13,600
ii) Reuse of non-EU non-compliant parts not permitted after 31a expires		Current exemption expires (unless renewed)								
Number of new needed	2,400	9,200	16,000	16,000	16,000	16,000	16,000	16,000	16,000	16,000
Number reused	13,600	6,800	0	0	0	0	0	0	0	0

If reuse of all parts is permitted by renewal of this exemption, only 15% of those assemblies sold would need new parts to replace the 15% of recovered parts that are too old or damaged to be refurbished. If this exemption is not renewed and expires on 22 July 2021, after this date, manufacturers would stop sales of refurbished products in the EU as they cannot guarantee compliance because of the difficulty of differentiating parts from medical devices that had been placed on the EU market before July 2014 from those that were previously sold to non-EU countries.

Table 10. Total impacts for 2020 to 2029 with and without exemption 31a.

Option	10 year totals 2020 to 2029		
	Numbers	**Total energy consumption (72 to 307 kWh / new housing)**	**Total new materials needed (assumes 10kg / new housing)**
i) Reuse of parts permitted		1.7 - 7.4 GWh	240 tonnes
Number of new parts	24,000		
Number reused	136,000		
ii) Reuse of non-EU non-compliant parts not permitted after 31a expires		10 - 42 GWh	1396 tonnes
Number of new parts	139,600		
Number reused	20,400		

The energy and new materials consumption without an exemption with option (ii) is nearly six times larger than option (i) when calculated over a ten year period.

These figures are estimates for the housings only which are one of the largest parts by weight, but many other parts are also reused. Some manufacturers will have parts in older returned assemblies that contain lead as solders or lead additives in PVC which they could also reuse with associated energy and raw materials savings if the exemption is renewed.

Overall health and environmental impacts depend on many other impacts apart from energy consumption and global warming emissions. For example, mining, refining and manufacture consumes energy predominantly by burning fossil fuels and these release hazardous substance (e.g. mercury, cadmium, lead and arsenic) to air and water. Manufacturing processes also create wastes. These impacts are all avoided if parts are reused so that new materials need not be made. One approach that can be used to estimate the size of overall impacts from manufacture of new parts such as aluminium housings can be determined using life cycle data from VHK which is used by the European Commission for eco-design preparatory studies[9]. The table below uses data for sheet / extruded aluminium alloys and is for mining, refining and manufacture life cycle phases as these phases have by far the largest impact, according to the VHK data. The impact of 1,156 tonnes is calculated because this is the difference in the quantity of new aluminium used without exemption 31a and with exemption 31a; i.e. 1,396 (all housing must be new without exemption 31a) – 240 (the quantity of new aluminium needed if 31a is renewed as replacements for the 15% that cannot be reused).

Table 11. Selection of impacts from mining, refining and manufacture of materials used for X-ray tube housings calculated using VHK Eco-tool

Impact	Quantity/kg Al produced	Impact for 1,156 tonnes*
Greenhouse gas emissions	11 kg CO2 eq.	12,716 kg CO2 eq.
Heavy metals emission to air	10 mg Ni eq.	11.56 kg Ni eq.
Heavy metals emissions to water	25 mg Hg/20	28.9 kg Hg/20
PAH emissions to air	97 mg Ni eq.	112 kg Ni eq.
Non-hazardous waste to landfill	452 grams	522.5 tonnes waste

* 1,156 tonnes is the additional aluminium required if this exemption is not renewed following on from calculations in Table 11 (i.e. 1,396 – 240 tonnes).
The data in the above table shows the size of some of the impacts that that are avoided by reuse of just one type of part that is recovered for reuse. In fact, all impacts are higher if new parts need to be made than in parts can be reused. The overall health and environmental

[9] Methodology for Ecodesign of Energy-related Products, MEErP 2011, Prepared for the European Commission, DG Enterprise and Industry, Unit B1 Sustainable Industrial Policy, contract SI2.581529, R. Kemna.

benefit from all recovered and reused parts will be significantly larger.