Date of submission: **17 July 2018**

1. Name and contact details

1) Name and contact details of applicant:

Company:	**COCIR**	Tel.:	**003227068966**
Name:	**Riccardo Corridori**	E-Mail:	**corridori@cocir.org**
Function:	**EHS Senior Manager**	Address:	**Blvd A Reyers 80, 1030 Bruxelles**

2) Name and contact details of responsible person for this application (if different from above):

Company:	_____	Tel.:	_____
Name:	_____	E-Mail:	_____
Function:	_____	Address:	_____

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2. Reason for application:

Please indicate where relevant:

- ☐ Request for new exemption in:
- ☒ Request for amendment of existing exemption in Annex IV
- ☐ Request for extension of existing exemption in
- ☐ 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: Could be combined with 31a

Proposed or existing wording: **Bis (ethylhexyl) phthalate, Dibutyl phthalate, Di-isobutyl phthalate and Benzyl butyl phthalate in spare parts recovered from and used for the repair or refurbishment of medical devices, including in vitro diagnostic medical devices, 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.**

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Similar to existing exemption 31a, this new exemption for the four RoHS-restricted phthalates will allow the reuse of recovered parts, regardless of where or when the medical devices they are originating from, were placed on the market. As already demonstrated for exemption 31a, and re-established again by the recent Waste Framework Directive, the environmental impacts of sending an old part to waste management and manufacturing a new replacement part always has a significantly higher overall impact than reusing the old part.

Allowing all recovered spare parts to be reused, provides a net environmental and health benefit and is paramount to establish a proper circular economy business model. Life Cycle Analysis has been used to demonstrate that the overall health and environmental impact of reuse is less negative that the overall impact of disposal and manufacture of replacement parts.

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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: category 8: medical devices such as MRI, CT, PET, SPECT, ultrasound imaging, patient monitors, In vitro-diagnostic 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 (please refer to existing exemption 31a for scope)

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
   ☒ DEHP ☒ DBP ☒ DiBP ☒ BBP

3. Function of the substance: Added to polymers, rubber, adhesives, paints and lacquers to confer flexibility and sometimes also added to polymers as a processing aid

4. Content of substance in homogeneous material (%weight): Between 1 and 50%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: No net change in amount within the EU
   Please supply information and calculations to support stated figure.
   All parts that are produced for medical devices after 21 July 2021 will not contain the four restricted phthalates. However recovered parts may contain these substances, although for the reasons explained in this exemption request, it will not be possible to determine how much. However, the phthalates that are in parts that are recovered from medical devices placed on the EU market before 21 July 2021 will not enter the EU market after 21 July 2021 as they will already be on the market. The exemption will extend the life of parts already on the market only. Some non-EU parts that contain phthalates will enter the EU market after this date, but also, a similar quantity of parts recovered from medical devices placed on the EU market before 21 July 2021 will also leave the EU. Overall, therefore, there will be no net change in the amounts of these phthalates present in the EU as the amounts entering will be similar to the amounts leaving.

6. Name of material/component: Bis (ethylhexyl) phthalate (DEHP), Dibutyl phthalate (DBP), Di-isobutyl phthalate (DiBP) and Benzyl butyl phthalate (BBP) which are added to polymers (including rubber), adhesives, sealants, paints and lacquers.

   The uses of these four phthalates are for example:

   - Plasticiser in PVC wire and cable insulation
   - Additive in rubber seals and O-rings used in connectors
   - Additive in rubber grommets that support cables
   - Plasticiser in PVC labels including those used on components such as capacitors
   - Added to give flexibility to adhesives used to seal capacitors and other electronic components

- Added to give flexibility to die attach material in integrated circuit packages
- As a processing aid in polymer mouldings

These applications are used in many types of parts of medical devices, a few illustrative examples are:

- X-ray tubes (include PCBs, cables, housing, etc.)
- Printed circuit boards (PCBs)
- MRI coils
- Detectors and components of detectors (e.g. radiation detectors)
- Transducers with associated cables

7. Environmental Assessment: _____
   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?

This new exemption is required for the same reasons that RoHS exemption 31a was required before the entry into force of restrictions for medical devices in 2014.

Many types of part are removed from used medical devices during refurbishment, repair, servicing or maintenance and then these parts are re-used for the repair, refurbishment, servicing and maintenance (referred to in this document as RRSM) of different medical devices. The RoHS Directive allows non-compliant spare parts to be used to repair non-compliant medical devices that were placed on the market before the entry into force of the restriction. According to the Commission Delegated Directive 2015/863, recovered parts containing phthalates can be used to repair, upgrade etc medical devices placed on the market before July 2021.

RoHS amendment 2017/2102/EU Article 4.5 also allows non-compliant parts recovered from medical devices that were placed on the EU market before 21st July 2014 to be used in medical devices to be placed on the market until 21 July 2024, but these dates however are applicable to the original six RoHS substances, not for phthalates which will not be restricted in Medical Devices until 21 July 2021.

Starting from 2021, new phthalate-free medical devices will be sold on the EU market. According to Commission Delegated Directive 2015/863 they could not be repaired with phthalates-containing spare parts but this is permitted only for MDs placed on the market before July 2021. At that time, the warehouses of medical device OEMs would be filled with recovered spare parts, that as shown below, cannot be declared phthalates-free (whether they comply or not). The consequence is that recovered and refurbished spare parts could not be

used to RRSM medical devices coming back from healthcare providers that were placed on the market after 21 July 2021.

Recovered and refurbished spare parts are as good as new parts, but they are lower cost to hospitals and are readily available. The global logistic created by manufacturers allows spare parts to be delivered worldwide to hospitals to RRSM medical devices to ensure the shortest possible downtime for the benefit of patients' health. Medical devices manufactured by COCIR's members are critical devices used in ER departments and other critical care facilities. Without the possibility to use recovered spare parts, newly manufactured spare parts will have to be used with the following implications:

- Higher costs for hospitals and clinics in EU
- Longer downtimes when new parts have to be made before the device can be repaired. Delays in availability of spare parts for faulty equipment has a direct impact on health of EU citizens due to delays in providing treatment
- Larger environmental impact due to the unnecessary wasting of older parts and manufacturing of new ones.

At the same time, after July 2021, used phthalates-free medical devices will be sent back to OEMs for refurbishment. Only recovered parts which may contain phthalates will be available in OEM's warehouses, and therefore refurbishment will be impossible as using new parts is not an option (this would make refurbished equipment too expensive compared to new equipment and to hospital budget).

Exemption 31a, published in 12/02/2016[1] allows the use of recovered spare parts from medical devices to be reused for RRSM operations regardless of when and where the medical devices from which the parts originated and whether they were previously placed on the market in the EU or in a non-EU country. Exemption 31a recognized the principle that the environmental benefits of reusing part are always higher than manufacturing a new part. 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.

The new exemption 31a for phthalates is needed to allow recovered spare parts to be reused instead of being wasted and to save global resources and the energy required for manufacturing new ones to replace discarded parts that could otherwise be used, as well as benefiting EU healthcare as explained above.

Phthalates free or not?

The restriction of the four phthalates was published on 31st March 2015. Subsequently, manufacturers have been endeavoring to determine whether parts and materials contain any of these four substances with the aim of replacing them wherever possible by 21st July 2021. However, it is frequently not possible to determine from suppliers if these substances are present in any parts used in medical devices before March 2015 as this restriction had not

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016L0585

been published and so there was no requirement from RoHS for suppliers to provide this information. Information on the presence of phthalates has not always been available to medical device manufacturers until long after March 2015. Due to long supply chains, it can take manufacturers of devices a considerable length of time to determine whether which plasticizer is used in components.

Although these four phthalates are also REACH SVHCs and REACH Article 33 requires suppliers to inform recipients if these are present at >0.1% of the articles (based on a different concentration limit to RoHS), it was understood (explained in the original ECHA Guidance on substances in articles) that the term "article" referred to the complete assembly as supplied. Most of the times this meant that these substances were present at less than 0.1% in complex equipment and so suppliers did not have to communicate the content down the supply chain. It has only been since the European Court of Justice ruling on the definition of articles and publication of new guidance by ECHA in 2017 that SVHC information from suppliers is based on the new interpretation.

As a result, medical equipment manufacturers are unable to determine from the supply chain whether these four phthalates were used in parts that they used in the past to manufacture medical devices and they wish to recover and reuse for RRSM of medical devices,. Previously, DEHP in particular was widely used in electrical equipment, but DBP, BBP and DiBP are also found to have been used. As there was no restriction of these substances before March 2015 and the concentration in the supplied article was below the threshold limit that triggered communication obligations according to REACH Article 33, suppliers had not collected information on the use of these four phthalates. As this was not determined when the components were originally used, it is now not possible to obtain this information from the supply chain as there are no records. It is also impossible to determine whether they are present by chemical analysis as all available methods are destructive which would prevent reuse of the parts[2].

Medical equipment manufacturers will only be able to use these parts after July 2021 to RRSM any product in need of repair, maintenance, servicing or refurbishment, if they know that they are fully compliant. As they cannot determine if DEHP, DBP, DiBP and BBP are present or not in recovered parts, it is not possible to determine compliance with the RoHS Directive and so no parts can be reused at all unless permitted by an exemption. An exemption will be needed that allows reuse of recovered parts that contain these substances. As will be shown in section 6, this exemption is justified because the environmental and health impact of allowing the exemption is less negative than not granting this exemption.

In addition, this exemption should preferably follow the form and structure of current exemption 31a to allow that all recovered parts can be reused.

Medical Devices are specialist relatively low volume equipment where each model is usually

[2] *Chemical analysis of phthalates is described in standard EN 62321-8:2017, Determination of certain substances in electrotechnical products. Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py/TD-GC-MS)*

sold worldwide. Those sold in the EU are usually identical to those sold in Asia and North America. Manufacturers of the more complex types of medical devices that are frequently refurbished for reuse, usually have only one refurbishment centre worldwide where all used equipment is shipped and refurbished. Parts are removed from equipment during the process and refurbished, and then used for refurbishment, repair, maintenance or servicing. Parts recovered from equipment that was originally been placed on the EU market before 21 July 2014 are identical to parts from medical devices that were previously sold outside of the EU and so had not been previously been placed on the EU market. Parts from these two sources (EU and non -EU) cannot be kept separately.

The following scenarios describe the RoHS status of parts recovered from medical devices (depending on when and where the MD was place on the market) and the possibility to use them for RRSM of medical devices:

Source of recovered part	RoHS compliance status of the recovered part	Medical device in which the recovered part is intended to be used for RRSM	Can the part be used and thanks to what?
MD sold outside of the EU before 21 July 2014	May contain all 10 RoHS substances	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES RoHS exemption 31a
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed, which clearly does not refer to "MD placed on the EU market" as per COCIR proposal
		New MD to be placed on the market between 22 July 2014 and 22 July 2024	NO RoHS article 4.5 as amended by Directive (EU) 2017/2102 does not allow for parts from non EU MD.
MD originally sold outside of the EU between 21 July 2014 and 21 July 2021	May contain phthalates	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES Annex II of Commission Delegated Directive (EU) 2015/863
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market after 22 July 2024	NO A new RoHS article 4.5 would be required for phthalates that does not limit to EU mMDs.

MD sold in the EU before 21 July 2014	May contain all 10 RoHS substances	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES RoHS exemption 31a
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market between 22 July 2014 and 22 July 2024	YES RoHS article 4.5 as amended by Directive (EU) 2017/2102
MD originally sold in the EU between 21 July 2014 and 21 July 2021	May contain phthalates	MD placed on the EU market before 21 July 2014	YES RoHS article 4.4
		MD placed on the EU market after 21 July 2014 and before 21 July 2021	YES Annex II of Commission Delegated Directive (EU) 2015/863
		MD placed on the EU market after 21 July 2021	NO NEW exemption 31a for phthalates needed
		New MD to be placed on the market after 22 July 2024	NO A new RoHS article 4.5 would be required for phthalates

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 RRSM medical devices that have been placed on the EU market after 21 July 2021 without this exemption. In fact, the situation will be 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 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 EU only) or not to use any recovered spare part for RRSM in the EU anymore to avoid the risk of unintentional non-compliance. This would have four negative impacts:

- No availability of refurbished medical devices in the EU will prevent some hospitals from obtaining refurbished equipment. As these hospitals cannot afford new equipment and the refurbished models would provide the diagnostic capability and treatment that they need, this would have a negative impact on healthcare.
- At least one third 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 can absorb the surplus, which would take many years.
- Less medical devices will be refurbished and so this will increase the quantity of waste generated in the EU
- That would be the end of the circular economy business model in EU for a frontrunning sector.

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

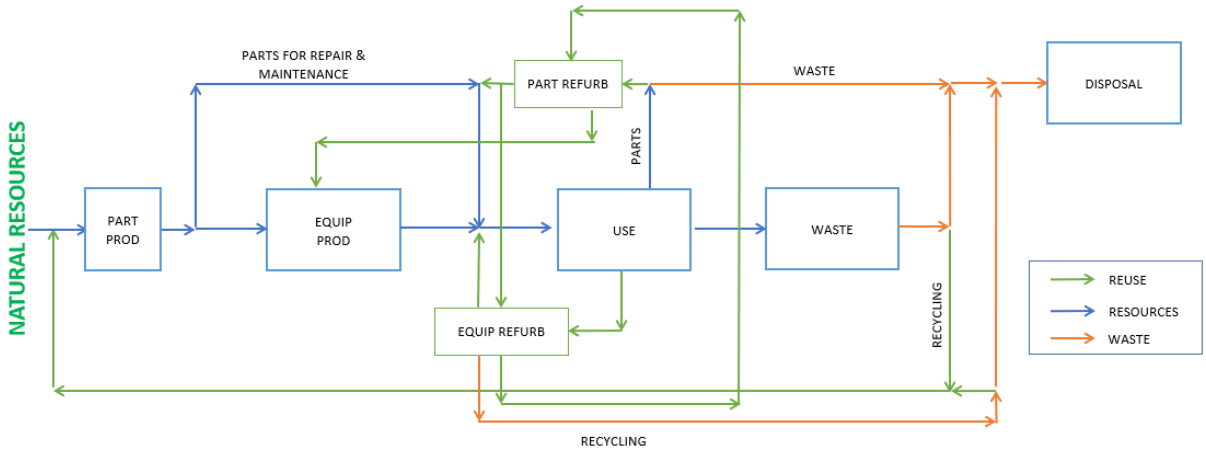
Phthalates are used as plasticisers.

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 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 equipment from 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 within the medical imaging sector[7].



An additional reason why refurbishment must be closed loop is from obligations of the Medical Devices Regulation, in particular regarding the need to ensure that only approved parts are used in the process (new or used), to ensure safety and performance.

_____

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" sounds similar to "fully refurbished" which has legally binding meanings in the Medical Devices Regulation. The correct term to use in this context is "refurbishment of medical devices".

☐ 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 it is impossible to determine now the quantities of phthalates that were used in the past in recovered parts. The total is likely to be less than 2 tonnes per year (estimated average of 0.1% of total of recovered and reused 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

As this exemption request relates to pre-existing components, there are only two scenarios to compare:

- With this exemption; and
- Without this exemption

With this exemption, it is possible to reuse all component parts that can be recovered. Without this exemption, due to the risk of non-compliance explained above in section 4, very few if any can be used. The two scenarios are compared as a life cycle assessment below:

With exemption	Without exemption
100% of recovered parts can potentially be reused	Most of the recovered spare parts cannot be used as the presence of phthalates is unknown and cannot be determined non-destructively (phthalate analysis is carried out by the method in EN 62321-8 which is solvent extraction from small particles of polymer followed by gas chromatography-mass spectroscopy).
Fewer new components will be manufactured and more MD will be refurbished.	Refurbishment of medical devices will have to use newly manufactured parts. However, this is not possible for older parts that have been discontinued and normally not economically-viable. Using 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. Therefore, fewer MDs will be refurbished for reuse in the EU.
Less waste as 100% of recovered undamaged parts can potentially be reused	All unusable recovered parts will become waste as it is not possible to determine their compliance
All refurbished equipment can be sold in the EU or elsewhere	Unless new parts are used (if available and probably not economically viable), 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. When medical devices are out of warranty, new spare parts may not be available and so could take up to 8 months to manufacture, if this is feasible at all)	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

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.

Health impacts include:

- Impacts of DEHP, DBP, DiBP and BBP compared with the impacts of alternative plasticisers on health of workers, users and the public
- Health impact of manufacture of replacement parts will cause emissions of global warming gases and hazardous substances and will consume resources and produce wastes. Refurbishment uses very small quantities of substances and energy in comparison and usually generates no waste.

Safety impacts include:

- Hospitals that cannot afford new equipment will often be 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 often proportion to the age of the equipment. Non-availability of medical devices, due to break-downs, can pose a serious safety risk to patients if they cannot be treated and this is delayed. 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 with a negative impact on patients.

Environmental impacts include:

- Comparative impacts of DEHP, DBP, DiBP and BBP compared with the impacts of alternative plasticisers on the environment
- Environmental impact of manufacture of replacement parts will cause emissions of global warming gases and hazardous substances and will consume resources and produce wastes. Refurbishment uses very small quantities of substances and energy in comparison and usually generates no waste.

Comparison of the overall impact with and without this exemption is mainly affected by:

- Heath impact on EU hospital patients from non-availability of refurbished equipment, delays in treatment due to inferior reliability of older equipment and longer timescales for obtaining new replacement spare parts compared to obtaining refurbished parts;
- The impact of manufacture of new parts instead of reuse

Health impact

Hospitals in all EU Member States have limited funds for new equipment and commonly purchase refurbished medical devices due to their lower price but ability to provide 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 has replaced an older device and possibly that another new or newer device

has also been obtained that can replace an older device. If refurbished medical devices are not available, the hospital would eventually have to buy a new device and this is likely to cause a delay 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 and the date when a new device could be purchased, patients will experience the following:

a) There is no 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 and due to demand at other hospitals, can result in delays to 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 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) Older equipment do not have the same performance as newer designs. For example new Ct scanners are equipped with dose reduction technologies, such as Automatic Exposure Control (AEC), and Image Iterative Reconstruction Engines that can reduce the radiation dose for patients of more than 80% with a higher image resolution.

   Better image quality is key for earlier diagnosis and 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 obvious benefit of a hospital being able to buy refurbished devices as so many unquantified variables affect patients' recovery and treatment costs.

Impact of new part manufacture and life cycle assessment

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 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. Often energy consumption creates the most harmful emissions and wastes due to coal and oil combustion for electricity generation and in furnaces. These energy sources are still the dominant energy source in the countries (e.g. USA, China, India) where most 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. Moreover some of such parts will contain RoHS substances due to RoHS exemptions.

A full life cycle assessment has been published that compares building new medical devices compared to refurbishment considering X-ray systems, MRI, PET and CT3. 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 refurbished systems are smaller than for new systems. Two examples are shown below:

Table 1. 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	
	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. LCAs have been published for some of the materials that are used in replacement parts and these include:

PVC, used as cable insulation of cable assemblies and to make electrical connections in complex subassemblies and to transducers. Various figures are published and three examples of global warming potential are given below:

[3] *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*

Table 2. Global warming impacts from PVC production, data from three sources

Source of data	Global warming impact from 1kg PVC
Publication reference 4	2.26 kg CO_2 equivalent
Publication reference 5	1.7 kg CO_2 equivalent
Publication reference 6 (VHK, EC MEErP study)	4 kg CO_2 equivalent

There will also be an impact from mining, refining and manufacture of the copper conductor of cables.

The impacts of printed circuit boards (PCB) have been calculated by VHK for the European Commission to be used for eco-design preparatory studies[6]. Impacts for several different types of PCB have been calculated. Example impacts from the manufacture life cycle phase from 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:

[4] *Life Cycle Inventory for PVC, Tim Grant, 26th August 2014*

[5] *Life Cycle Assessment, PVC for electric cable application, Dr.-Ing. Maiya Shibasaki, DOW*

[6] *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.*

Table 3. Selected 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 parts can be reused. Zlamparet et al. 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[7] that about 2200 tonnes of parts and 1000 tonnes of equipment (total 3200 tonnes) are refurbished and then reused in the EU annually. Many of these parts such as PCBs and cable assemblies 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.

[7] *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*

Reuse of parts will continue into the foreseeable future but as old parts reach end of life and parts made without phthalates become available for reuse, the quantity of phthalates in circulation will gradually decrease to zero. This means that with this exemption, about 3200 tonnes of medical equipment and collected used parts will be refurbished and can be reused in the EU, but the total quantity of phthalates present in these parts will gradually decrease annually as the proportion of recovered parts made after July 2021 increases from zero in 2021 to 100%, probably by 2036. Without this exemption, it will be impossible to reuse recovered parts in EU medical devices with the implications described in this document.

The impact of not granting this exemption would also be for each year, a need for an additional 2200 tonnes of new parts to be made with its associated impacts mainly for repairs, maintenance and servicing. If we assume that 90% of parts are PCBs (30% 1 or 2 layer, 30% is surface mount devices and 30% ICs) and the rest is PCB cables (50% PVC and 50% copper wire), using the VHK ecodesign impact data, the impacts will be:

Table 4. Selected EU impacts on repair, maintenance and servicing medical devices in the EU without this exemption. Calculations provided in Annex I

Impact	EU total
Global warming impact	473,970 kg CO_2 eq
Heavy metals emissions to air	654 g Ni eq
Waste, hazardous/ incinerated	1,410 kg
Noon-hazardous waste landfilled	9680 kg

In addition there are other impacts from new parts manufacture such as particulate and POPs emissions, emissions to water and energy and resource consumption that would not occur if this exemption is granted. There are **no negative impacts** from the continued use of DEHP, DBP, DiBP or BBP in already 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.

Overall Life Cycle Assessment

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

- The results of an LCA study 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
- Repairs may be delayed if refurbished recovered parts cannot be used. This will vcause 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 expensive types of medical device because refurbished equipment is available at up to 50% discount that provides the medical diagnostic and treatment capability that they require. Without this exemption, the availability of such equipment would be very much diminished so that hospitals are unable to obtain this equipment with resultant negative health impacts on patients. If they were to buy new at the much higher cost, this will prevent them buying other medical equipment as their budgets are always limited and the non-availability of this equipment would have a negative health impact.

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

Not applicable to this exemption as recovered used parts and new parts have identical reliability

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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.

All new components of medical devices that are sold in the EU and which are placed on the global market will not contain DEHP, DBP, DiBP or BBP from 21 July 2021 at the latest. This is because most medical devices are sold globally and are not designed only for the EU market. Until this date a decreasing number of parts will contain DEHP, DBP, DiBP or BBP as these substances are replaced by alternatives.

Medical devices are returned to manufacturers for refurbishment after about 5 – 7 years and so those being returned until about 2028 (7 years after 2021) are

likely to contain DEHP, DBP, DiBP or BBP in component parts that might be recovered for reuse, although in gradually decreasing quantities over this period.

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

Substitutes will be available for use in new medical devices by 21 July 2021. Medical equipment placed on the market before 21 July 2021 that contain DEHP, DBP, DiBP or BBP are likely to reach first user end of life until about 2028 at the latest and so any parts recovered after this date are much less likely to contain DEHP, DBP, DiBP or BBP.

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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 – DEHP, DBP, DiBP and BBP are SVHCs in Annex XIV. However, these substances are no longer used in the EU to manufacture parts of medical devices. Parts either have already been made and are in use and will be reused in the future. Parts may be made outside of the EU until 2021

- ☒ SVHC
- ☒ Candidate list
- ☐ Proposal inclusion Annex XIV
- ☒ Annex XIV

☒ Restriction

☒ Annex XVII – restricted only in childrens' and childcare products so not applicable

☒ Registry of intentions – a restriction on materials with prolonged skin contact has been proposed. Most parts of medical devices do not have prolonged or frequent skin contact and so would be out of scope. If this restriction enters force in the future, any parts which have PVC that may be used with prolonged skin contact will not be reused.

☒ Registration – All four phthalates have been registered in the EU.

DBP - https://echa.europa.eu/registration-dossier/-/registered-dossier/14862

DiBP - https://echa.europa.eu/registration-dossier/-/registered-dossier/13519

DEHP - https://echa.europa.eu/registration-dossier/-/registered-dossier/15358

BBP - https://echa.europa.eu/registration-dossier/-/registered-dossier/12721

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? _____
   ☒ No. Justification: Large overall negative environmental and health impact
2. Can the substance named under 4.(A)1 be substituted?
   ☐ Yes.
   ☐ Design changes:
   ☐ Other materials:
   ☐ Other substance:
   ☒ No.
   Justification: Large overall negative environmental and health impact
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: See section 6 above
   2) Health impacts: See section 6 above
   3) Consumer safety impacts: Parts made with phthalates and alternatives must be equally safe to enable manufacturers to obtain Notified Body approval of medical devices, as required by the Medical Devices Regulation. The only potential negative consumer safety impact would be if there are delays in repair of non-functioning medical devices due to delays in sourcing new parts if refurbished parts cannot be used. Delays in provision of medical treatment can have serious consequences.

⇨ Do impacts of substitution outweigh benefits thereof? Yes, see section 6
Please provide third-party verified assessment on this:

Submitted as separate document

Availability of substitutes:

a) Describe supply sources for substitutes: New parts are made by the same manufacturers as those that make medical devices until production of the

designs that use them ceases, although sufficient for warranty periods (2-5 years) are usually stockpiled.

b) Have you encountered problems with the availability? Describe: Yes. After warranty periods end, the availability of new parts declines as these cease production.

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

☒ Yes ☐ No If a new part has to be specially made as a one-off, this will be considerably more expensive which the hospital will have to pay for.

d) What conditions need to be fulfilled to ensure the availability? All substitutes must provide the same or better performance as the restricted phthalates in order to obtain Notified Body approval of medical devices, as required by the Medical Devices Regulation

(C) Socio-economic impact of substitution:

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

☒ Increase in direct production costs – additional parts would need to be made to replace those that cannot be used

☐ Increase in fixed costs – unlikely

☐ Increase in overhead - unlikely

☒ Possible social impacts within the EU – increased costs from making new parts as spare parts would be passed on to EU hospitals that buy refurbished equipment and spare parts. EU citizens would be negatively affected if EU hospitals were unable to buy refurbished equipment. These issues could also cause delays in treatment or force patients to travel further to different hospitals.

☐ Possible social impacts external to the EU - none

☐ Other: _____

⇨ Provide sufficient evidence (third-party verified) to support your statement:

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:
