Exemption Renewal Form - Exemption 15, Annex IV

Date of submission: **15 January 2020**

This dossier is submitted by COCIR for category 8 medical imaging devices and supported by JBCE. As the same exemption is also needed by category 9 equipment, JBCE is the contact point for such category. Contact details are reported here below.

1. Name and contact details

1) Name and contact details of applicant: Medical Imaging Devices

Company:	**COCIR**	Tel.:	**00327068966**
Name:	**Riccardo Corridori**	E-Mail:	**corridori@cocir.org**
Function:	**EHS Policy Senior Manager**	Address:	**Blvd A. Reyers 80, 1030 Bruxelles**

2) Name and contact details of applicant: Medical Devices and Category 9 equipment (non-industrial).

Company:	**JBCE – Japan Business Council in Europe aisbl**	Tel.:	**02.286.5330**
Name:	**Takuro Koide**	E-Mail:	**koide@jbce.org, info@jbce.org**
Function:	**Policy Manager**	Address:	**Rue de la Loi 82, 1040 Brussels, Belgium**

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: 15

Proposed or existing wording: Lead in solders for bonding to ultrasonic transducers

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Medical ultrasound transducers are very sensitive to the method of bonding electrical connections and any change in bonding alloy or bond design can have a detrimental effect on image quality. Manufacturers design new transducers with lead-free bonding methods, but it has not been possible, for technical reasons, to redesign all types of transducer without lead-based solders. Those types of transducer that require lead solders cannot be replaced by different types of transducer as each model has unique characteristics and performance. Some medical diagnostic and treatment procedures are possible only with one or a very few types of transducer. Further research is needed to replace lead solders but this will take many years and EU citizens' health may be negatively affected if engineering time is spent on substitution rather than developing innovative new transducers that give superior diagnostics and treatment performance.

Information on category 9 applications is not included in this document and will be available from JBCE

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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 ultrasound transducers

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

☐ 1
☐ 2
☐ 3
☐ 4
☐ 5
☐ 6
☐ 7
☒ 8
☒ 9
☐ 10
☐ 11

b. Please specify if application is in use in other categories to which the exemption request does not refer: monitoring and control instruments in industry

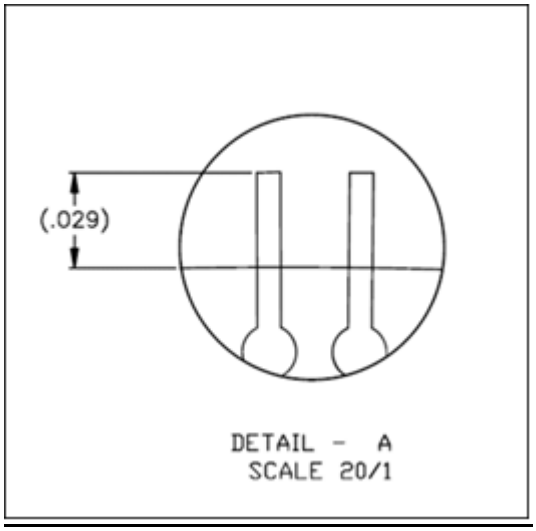
c. Please specify for equipment of category 8 and 9:
The requested exemption will be applied in
☐ monitoring and control instruments in industry
☐ in-vitro diagnostics
☒ other medical devices or other monitoring and control instruments than those in industry

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

3. Function of the substance: Electrical connections to medical ultrasound transducers

4. Content of substance in homogeneous material (%weight): 36 – 40%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: Estimated to be less than 100 grams and probably about 20 grams per year
Please supply information and calculations to support stated figure.
Data from one manufacturer is that they solder 259,0928 solder bonds per year (calculated from the numbers of transducers sold and bonds per transducer). The flying leads that are soldered are as follows:



A calculation of volume of solder used (density of SnPb of 8.4 g/cc) calculates 0.0000279 g/solder joint. We then added some additional solder during the solder process and that was calculated to be 0.0000125 g. This gives a total of 0.0000404 g / solder joint. So for 259,0928 solder bonds, of which about 20% are in transducers placed on the EU market, this gives a total of 21 grams of solder with 37% lead metal and so 7.7 grams of lead metal per year.
The quantities of lead in solder used by other manufacturers is not known but we expect will be at least as much again and so the total quantity would be of the order of 15 – 20 grams per year.

6. Name of material/component: tin/lead alloy

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?

Medical ultrasound transducers are made from lead zirconate-titanate (PZT) ceramic or from single crystal piezoelectric materials such as lead magnesium niobate – lead titanate (PMN-PT) which must be accurately cut and mounted in the correct orientation to achieve the optimum performance. Electrical connections must be made to the two ends of each element the ceramic or crystal to apply an electric field or to measure the electric field across the material. There each transducer will have 2 to 512 connections and most have more than 100 solder bonds. The bonds must not interfere with the operation of the transducer as this can cause distortion of images. Crystals, as produced, have optically flat surfaces that are difficult to make reliable bonds but the bonding surface can be etched to improve adhesion. Some manufacturers of piezoelectric materials produce

piezoelectric ceramics or crystals that are pre-poled and which are supplied to medical device manufacturers with the two bonding surfaces metallised to enable electrical connections to be made. Commonly used metallisations include thin-film chromium/gold, titanium/gold, chromium/ nickel/copper and thick film silver. The coating process is:

- Chromium or titanium are evaporation coated onto the piezoelectric material surface because these metals form a relatively strong bond with very good adhesion and low electrical resistivity. They cannot however be used for bonding to solder because as soon as these are removed from the coating chamber, which contains a high vacuum, and exposed to air, they will oxidise to form an electrically insulating surface that is difficult to remove or make bonds. As a result, the most common approach is to coat the chromium or titanium layer in the vacuum chamber with an over-layer of gold or first a nickel layer followed by copper. Gold is used because it will not oxidise or tarnish when removed from the vacuum chamber and can easily be soldered, although technical issues can occur (as described in section 6). PVD Silver and CuNi coatings are also used and the PVD Au, Ag or CuNi layers are typically 1 micron thick.
- Thick film silver applied by screen printing is used by some piezoelectric material manufacturers, typically 10 microns in thickness. The films are formed by heating a mixture of silver and glass particles to 800°C. Piezo materials must be poled after this process is carried out. Adhesion to solder can however be an issue.

Commercial medical transducers are produced in a variety of designs that depend on the medical diagnosis required. Very small devices are made with single piezoelectric elements that can be inserted inside arteries, but most have multiple elements in arrays that are used to create a two dimensional image. Two and three dimensional arrays are used, each element of an array is very small so that making a solder bond without damage to the element requires skill and experience. The ceramic and single crystal materials are brittle and can be damaged by the thermal shock caused by the rapid temperature rise caused by soldering.

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

All of the following are essential:

- Electrical connections must be made to piezoelectric materials without imposing strain on the ceramic or crystal as this will cause distortion of images. Also excessive strain due to sudden rapid temperature rise can cause cracks in ceramics and single crystal materials.
- Medical ultrasound ceramic and crystals oscillate at frequencies typically from 1 MHz to 18 MHz with some niche uses using over 100MHz. The bond and the

metallisation must not be detrimentally affected by this severe vibration for the normal lifetime of the equipment.

- Medical ultrasound transducer manufacturers obtain pre-poled crystals from suppliers. The bonding process should ideally not cause depoling or a phase change to the crystal structure, but repoling after bonding is possible if the equipment is available. PMN-PT crystals experience phase changes in the range 80 to ~130°C and have Curie temperatures of about 85 to 170°C, depending on composition. The Curie temperature for PZT suitable for medical ultrasound can be <200°C[1]
- Medical ultrasound modules used by medical personnel may have one piezo element or an array of typically up to 256 piezo elements, all of which must be bonded without causing any distortion or damage to any of the elements (2 solder bonds to each element),

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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.)

Although the majority of ultrasound transducers are returned to the manufacturer, a significant proportion, due to the small size, reach disposal and recycling via other routes (i.e. the WEEE Directive) so a closed loop does not exist for this application.

2) Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling
☐ Article is collected and completely refurbished for reuse
☐ 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 _____

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[1] Material PIC153 from http://www.piezo.ws/pdf/Piezo_Materials_Piezo_Technology_Piezo_Components.pdf which is reported to be suitable for medical imaging (see page 13).

☒ In articles which are recycled < 100grams lead per year (total is declining each year as a larger proportion of transducer made >10 years ago would have used lead solder than today.

☐ In articles which are sent for energy return _____

☐ In articles which are landfilled _____

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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

Since medical device manufacturers learned that medical devices would be included in the scope of RoHS, they have carried out research into alternative bonding methods such as with lead-free solders and conducting adhesives. Since 2014 when medical devices entered scope, research into new designs and models has avoided using lead-based solders and have used lead-free solders or conducting adhesives where this has been technically possible and products have been proven to be reliable. This has affected the designs of new products which need to be tested for reliability, then clinical trials must be carried out and finally assessed by a Notified Body for Medical Devices Regulation approval. This is a time consuming and complex process which has been possible for new designs, but it has not been possible to use lead-free solders or conducting adhesives as drop-in replacements with the many types of older models that are on the market and are still needed by EU hospitals. A limitation in the number of technical experts and design engineers needed to carry out the redesign research is a significant barrier to substitution as was pointed out by the ERA study into the ability of category 8 and 9 manufacturers to modify their products[2]. Unfortunately, lead-free solders and conducting adhesives cannot be used as drop-in replacements for lead-based solders as is explained below and so it has not been feasible to substitute for lead in all of the designs of ultrasound device currently used in the EU. The justification for this exemption is that without this exemption, all older designs could not be sold in the EU and this would have a negative impact on healthcare in the EU as is explained below.

Substitute options

Lead-free solders

Piezoelectric ceramics and crystals are brittle materials that are easily damaged. Cracks caused by thermal shock will prevent them from functioning so that they become waste. The bonds to the two ends of the piezo material are hand soldered using a soldering iron. This can cause a very rapid temperature rise which imposes stresses on the piezo material and can cause cracks. The people who carry out the soldering process are extensively trained so that

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2 http://ec.europa.eu/environment/waste/weee/pdf/era_study_final_report.pdf (see page 5).

they are able to minimise the thermal shock to avoid cracks. However, thermal shock will be more severe – and cracking more likely – if a solder with a higher melting point is used and also if the wetting time is longer so that the soldering iron needs to be held against the ceramic for a longer period.

Although many types of lead-free solders have been developed, all of the alloys typically used for soldering electronic components have both a higher melting point and longer wetting times than tin/lead solders. Comparison of the melting temperatures of some commonly used electronic solders and tin/lead shows:

Solder	Melting point
Sn37Pb	183°C
Sn3.5Ag0.5Cu	217 °C
Sn-3.5Ag-3Bi	206 – 213°C
SnCu	227°C

Note that Sn-3.5Ag-3Bi is not a eutectic solder and so the soldering temperature must exceed the upper end of the range (i.e. >213°C) for effective solder bonding.
Comparative solder wetting tests have been published by Asahi (a solder manufacturer)[3] in which a variety of alloys were compared by wave soldering a standard PCB using a soldering temperature of 245°C.

Alloy composition	Wetting time (seconds)
Sn37Pb	0.6
Sn0.7Cu	1.0
Sn3.5Ag	1.4
Sn3.5Ag3.0Bi	1.7
Sn4Ag0.5Cu	1.9

Wetting times also depend on temperature, so the wetting time for SnAgCu could be reduced but only by increasing the temperature which increases the risk of cracking the brittle ceramic and depoling the transducer and also increasing the substrate dissolution rate (if the thin evaporated metal coating is completely dissolved, as can occuir at higher temperature, this will cause bond failure). Ultrasound manufacturers may have the capability to repole ceramics or crystals, but once assembled into transducers with electrical connections, research has shown that poling can cause cracking of the piezo material and so this not always possible. This is a particular issue with transducers that use multiple piezo elements and some designs have for example 160 discrete elements that must be bonded. If only one of these were to fail, then the transducer becomes waste as it cannot be repaired.
Manufacturers have also evaluated lower temperature solders; either BiSn or indium based,

[3] http://www.asahisolder.com/Publication/Comparative.pdf

but all were found to have inferior reliability (i.e. bond failure during testing).

Piezoelectric crystals are metallised using relatively thin metallisation layers (as described above). It is important that solder bonding does not completely dissolve all of these layers as solder will not wet the piezoelectric crystal material and so any initial bonding will fail. Of the metallisation materials available; gold, silver or copper over nickel, all dissolve fairly rapidly in molten tin alloys. The rate of dissolution is proportional to the temperature, wetting time and also to the tin content of the solder. Most lead-free solders are mostly tin (95 – 99%), have higher melting points and need to be molten for longer to form a bond and so substrate dissolution is faster than in eutectic tin/lead with only 63% tin and at a lower temperature.

Conducting adhesives

Conducting adhesives are now used as one of the substitute options for new designs, but this is not a drop-in replacement and so is used only in new modules that are designed to be able to be reliably bonded using these materials. Manufacturers have found that conducting adhesives are usually not “backward compatible” with modules that were designed with tin-lead solder bonds as the conducting adhesive bonds can have reliability issues or they detrimentally affect the image quality.

Ohmic contacts

This option is used by some manufacturers for some newer designs of transducers, but the technology used is proprietary and so only some manufacturers have this capability. Also, it is not backward compatible and so is unsuitable for transducers designed with tin-lead solder bonding.

Gold wire bonding

Used for a few designs, but cannot be used with all designs and is not backward compatible and so is unsuitable for transducers designed with tin-lead solder bonding.

Impact on healthcare of non-availability of many types of ultrasound transducers

Medical device manufacturers are continuing to research substitutes for the many older designs of transducer, but for the designs that still use lead-based solders this has so far not been technically possible. Hospitals in the EU need and use many different types of ultrasound transducer and each design is intended for specific medical diagnostic procedures. Variables include:

- Number of elements in module from one to 256
- 2, 3 or 4D imaging
  - 2D – scanning to generate a 2D image
  - 3D – scanning areas sequentially to generate a 3D image
  - 4D – live 3D imaging in real time
- Frequency – single or a range:

Characteristic	High frequencies	Low frequencies
Resolution	Good	Poor
Penetration depth	Weak	Strong
Scanning depth	Shallow	Deeper

- Array design include:
  - Phased arrays - Electronically steered system where many small elements are electronically coordinated to produce a focus wave front
  - Linear array - Many small electronically coordinated elements used to produce a rectangular image.
  - Curved array – the array of elements mounted onto a convex surface rather than a flat surface.
- Other characteristics are the field of view, aperture size, suitability for biopsies and the applications which the transducer is capable. Applications include:
  - Cardiac
  - Breast imaging
  - Liver
  - Obstretrics
  - Abdominal
  - Thyroid
  - TV/TR = Transvaginal / Transrectal for fetal/gynecology and prostrate scanning
  - TCD = Transcranial Doppler, used to monitor cranial blood flow velocity
  - TEE = Transesophageal echo, used internally for cardiac imaging
  - Vein and artery applications.
  - EUS = Endoscopic ultrasonography for diagnosis of pancreas and biliary tract

Medical ultrasound transducer design has been reviewed and a publication gives a summary of the variety of designs used and their medical applications[4]. This publication illustrates the very large variety of designs that are needed to diagnose and treat patients.

In addition, there are many types of ultrasound scanner used by EU hospitals and clinics and most are designed to be used for certain types of imaging applications, for example foetal imaging.

Transducers are usually designed to be used with one type of scanner and so EU hospitals

[4] Ultrasound Transducer Selection in Clinical Imaging Practice, Thomas L. Szabo & Peter A. Lewin, 2013. Downloaded from https://onlinelibrary.wiley.com/doi/full/10.7863/jum.2013.32.4.573

that already own a scanner and want to buy additional transducers can usually only use those types that are designed to be used with their scanner. If a transducer were to fail, they can be replaced as spare parts but if a different type of transducers is needed then this would be regarded as new electrical equipment. It is relatively straightforward to use additional transducer probes with some manufacturer's scanners, but this is not always the situation so with some models more significant changes are needed with some models of scanner to accept new transducers.

If this exemption is not renewed, some EU hospitals will not be able to buy additional transducers for their scanners which will have a negative impact on healthcare[5].

Overall health, safety and environmental impact without renewal of this exemption

Ultrasound transducer manufacturers have not yet been able to replace lead solder in all types of transducer that are used in the EU. The work required to replace solder bonding requires skilled engineers and takes at least one year for each type of transducer. This assumes that the engineers work on nothing else, such as new product development, which is an issue as explained below. Very few suitably trained and experienced engineers are available as they need to have experience in bonding to piezoelectric elements because the bonding method and design can detrimentally affect image quality or reliability. Typically, each manufacturer would have at most, the resources to substitute lead solder in one type of transducer at a time and this will take one year. However, one manufacturer could have 10 – 15 types of transducer that use lead solders and so the timescale (without the time needed to gain approvals) is at least 10 – 15 years and only if this proves to be technically possible which will not be the case with all older designs. If manufacturers were forced to stop selling these types of transducer in the EU, this would have two negative impacts on EU hospitals and clinics, as explained below.

Negative impact 1: Impact of restriction of choice for EU hospitals and clinics

As stated above, if this exemption is not renewed, one impact would be that some EU hospitals will not be able to buy additional transducers for their ultrasound scanners that they already own. They might wish to buy additional transducers for their different diagnostic capabilities to treat more patients and for more conditions. Without this, some patients may not be treated by the optimal methods or they may need to travel further to different hospitals.

The many ultrasound scanners that are on the EU market have different performance characteristics, as well as being designed for different diagnostic applications and treatments. If some scanners and their transducer probes were no longer available, as these transducers require exemption 15, this would limit the choice available to EU hospitals and clinics.

Example 1: Some models of ultrasound transducer give superior performance to other types of transducer including those types that use lead-free bonding. One example is the Philips

[5] Replacements for defective transducer would not be affected as these are spare parts, but supply of additional transducers of different types that are designed for different diagnostic capabilities could be prevented.

C5-1 transducer which has exceptional performance in a wide range of abdominal imaging applications. Specific examples of medical procedures include:

- Scanning "Technically Difficult Patients" where failed examinations with conventional technology on patients with high BMI (Body Mass Index) were successfully imaged with the Philips C5-1 transducer (but cannot be imaged with other transducer types),
- Liver Assessment where the imaging using the C5-1 transducer in combination with contrast agent imaging and shear wave elastography allows clinicians to assess liver fibrosis and characterize lesions,
- Vascular and Fusion Navigation where the C5-1 transducer provides real-time fusion with historical CT/MR data to reduce repeat costly examinations and allow collaboration with other modalities to facilitate treatment planning and interventional procedures.

The loss of these capabilities in EU hospitals and clinics would have a negative impact on patients. A list of applicable publications describing medical diagnoses using the C5-1 is provided in Appendix I. Most of these publications are written by medical practitioners and provide more details of how this transducer can achieve performance that is not possible with alternative transducers.

Similarly, a pump for medical purposes is one example of the medical devices in which the same principles (piezoelectric elements) is used. The pumps for medical purposes require the administration of drug solutions with a high degree of accuracy. Air bubble sensors are useful for detecting the presence or absence of air bubbles in the drug solutions, and for preventing excessive bubbles from being administered to the patient by stopping the pump if a certain amount of bubbles is entrained. Typical pumps for medical purposes incorporate a bubble sensor. If the bubble sensors were no longer available, as these transducers require exemption 15, this would limit the choice available to EU hospitals and clinics.

Negative impact 2: Inhibiting new product innovations and development

This section explains an additional implication of not renewing exemption 15. Diverting engineers away from new product development to replacing lead solders in ultrasound transducer could negatively affect future health of EU citizens. This is because the only reasons for development of new medical devices is to produce new designs with superior diagnostic capability and improve treatments, whereas substitution for lead in an existing product gives no medical treatment benefits to EU patients.

One recent example of a newly developed ultrasound product (this was not a substitute for a lead soldered model) that illustrates the benefits of developing new technology is the eL18-4 ultrasound imaging transducer. The eL18-4 has enabled a wide range of new capabilities that allows exceptional imaging performance providing critical clinical information across a wide range of applications. Development of the eL 18-4 required a significant effort whereas the engineers who developed this product would not have been able to do this if they were diverted to substitution work with existing products, which as explained above, is not straightforward and is very time consuming. These engineers are not able to do both. Appendix II lists

publications that describe the medical benefits of this new transducer. Most were written by medical practitioners.

Another recent example that illustrates the benefits of developing new technology is with MRI. A new innovation has been to develop digital coils to replace analogue coil designs. One manufacturer claims that digital coils have superior signal to noise ratio than analogue designs[6]. This type of improvement in performance results in clearer images that enable doctors to be able to detect tumours and other harmful conditions much earlier. In turn, this improves the likelihood of recovery while recovery is also likely to be faster and so incur smaller costs to hospitals. This type of development would not be possible if the engineers were diverted to redesign existing products for compliance purposes, but without performance improvement.

Quantitative life cycle comparison of the two scenarios of a) developing new medical devices or b) replacing lead in existing medical devices is not possible as the positive and negative impacts of each scenario are not directly comparable with each other and some impacts are for hypothetical future developments and so cannot be quantified. However, an illustrative comparative LCA can demonstrate which scenario is preferable overall as is shown below:

Impact	Develop new medical devices	Replace lead solder
Mining, refining and production of materials	Impossible to quantify as materials of new designs will be product dependent. However, new products should usually have a smaller overall impact to older designs because medical device manufacturers try to avoid using hazardous substances in new designs as required by Medical Device Regulation standards[7]	Alternatives to lead are not benign. The US EPA comparison of lead solders with lead-free solders showed that the impacts overall were different and that neither could be determined to be superior[8]
Use phase	Fewer deaths, faster recovery, lower hospital costs. Number of each will be product dependent. However, it is usually impossible to quantify as there are so many variables that also affect these variables as well as the effect of a new design[9].	No impact, unless the substitute is less reliable then patient health would be negatively impacted

[6] https://www.philips.co.uk/healthcare/education-resources/technologies/mri/dstream

[7] This is required by Medical Devices standard EN 60601-1-9:2007 “Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design”

[8] https://www.epa.gov/sites/production/files/2013-12/documents/lead_free_solder_lca_summary.pdf

[9] These include changes in personal affluence, improved medicines, reduction in pollution, education, food, etc.

Impact	Develop new medical devices	Replace lead solder
End of life	All medical devices are collected and recycled as required by the WEEE directive. As medical devices such as ultrasound scanners are used only by professionals, 100% are likely to be recycled. The impact of recycling new products is likely to be similar to older designs although there may be a smaller overall impact as manufacturers try to avoid hazardous substances in new designs[7].	Recycling of ultrasound transducers is carried out for metals recovery using smelters. This process is designed to accept a wide variety of materials including lead which is safely recovered with emissions very closely controlled to comply with the EU Industrial Emissions Directive. Lead recovery will be necessary as lead is present in other RoHS-exempt forms. Therefore the comparative impacts from recycling transducers with lead or without lead is likely to be very small.

The overall result from the three life cycle phases for the two options is therefore:

Impact	New medical devices	Replace lead
Mining, refining and production of materials	Potential positive benefit	Neutral according to US EPA
Use phase	Potentially a very large positive benefit	No effect or slightly negative
End of life	Potential positive benefit	Neutral or slightly positive

Although it is not possible to compare quantitatively the development of a hypothetical new medical device with replacement of lead solders in ultrasound transducers, it appears that new medical device development would give a significant overall benefit compared to lead replacement in an existing design of transducer.

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

Substituting lead-free solders for lead solders can cause inferior reliability as shown in many publications[10].

[10] Ultrasound is effectively high frequency vibration. Publications include: High-Frequency Vibration Tests of Sn-Pb and Lead-Free Solder Joints, D Di Maio and C Hunt, NPL report MAT 2, August 2007, Vibration Durability Investigation for SAC and SnPb Solder: Based on JCAA/JG-PP Lead-Free Solder, Project Test Results,

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.

Since 2014, all new designs of ultrasound probes have been designed with lead-free electrical connections and these have replaced some old models that have been phased out. However alternative bonding methods are not drop-in replacements and it has not been technically possible to replace lead solder in many types of transducer.

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

Gradually in the future, new transducer designs will be developed that have superior performance to old designs. As these are developed, it will be possible to phase out old models except where they are needed by EU hospitals that have older types of scanners that need these probes either as replacement spare parts or as additional probes. This is expected to take about 7 – 10 years.

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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
  - ☒ Candidate list – lead metal was added June 2018
  - ☐ Proposal inclusion Annex XIV
  - ☐ Annex XIV
- ☐ Restriction
  - ☐ Annex XVII
  - ☐ Registry of intentions
- ☒ Registration – lead metal has been registered – see https://ila-reach.org/our-substances/lead-metal/ and

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CALCE Electronic Products and Systems Center, 2006 and T. Woodrow, JCAA/JG-PP Lead-free solder project: Vibration and Thermal Shock Tests", April 2006, drop tests: Heaslip, Ryan, Rodgers & Punch Stokes Research Institute and University of Limerick, "Board Level Drop Test Failure Analysis of Ball Grid Array Packages" and Weiping Liu and Ning-Cheng Lee, "The Effects of Additives to SnAgCu Alloys on Microstructure and Drop Impact Reliability of Solder Joints", Journal of Materials, July 2007. Thermal fatifure, e.g. IPC study, abstract from https://www.itri.co.uk/solders/solders/study-compares-themal-fatigue-of-sac105-and-sac305-solders

https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

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: Drop-in replacement bonding is not technically possible and so time is needed to develop new ultrasound probes. This relies on the availability of suitable trained engineers, should not impede innovation of new medical devices and will take many more years
2. Can the substance named under 4.(A)1 be substituted?
   - ☐ Yes.
     - ☐ Design changes:
     - ☐ Other materials:
     - ☐ Other substance:
   - ☒ No.

     Justification: Drop-in replacement bonding is not possible and so time is needed to develop new ultrasound probes that can use different bonding materials and are different designs. This relies on the availability of suitable trained engineers and should not impede innovation of new medical devices and will take many more years
3. Give details on the reliability of substitutes (technical data + information): See answer to Q6 (B).
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: See answer to Q 6 (A)
   2) Health impacts: See answer to Q 6 (A)
   3) Consumer safety impacts: Not applicable

⇨ Do impacts of substitution outweigh benefits thereof? See answer to Q 6 (A)
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Many possibilities are described in section 6 (A) above and all are readily available

b) Have you encountered problems with the availability? Describe: No

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

☐ Yes ☒ No

d) What conditions need to be fulfilled to ensure the availability? Availability is not an issue

(D) Socio-economic impact of substitution:

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

☐ Increase in direct production costs

☐ Increase in fixed costs

☐ Increase in overhead

☐ Possible social impacts within the EU

☐ Possible social impacts external to the EU

☒ Other: Without this exemption, fewer types of ultrasound probes would be available. This would negatively affect EU citizens, for example, if they have to travel further to a different hospital to be treated or treatment may take longer if the optimal type of ultrasound probe is not available. If medical device manufacturers were forced to redesign existing models instead of developing new innovative products, this would negatively affect EU citizens' health, to some extent, in the future. . There were 800,000 ultrasound scans carried out in England per month in the year 2018/19[11]. The number of scans carried out in the EU, based on population is likely to be 10 times as many at about 8 million scans per month or up to 48 million per year. Ultrasound imaging is a very widely used diagnostic tool and so any reduction in availability could potentially harm the health of EU citizens.

⇨ 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:

_____

[11] https://www.england.nhs.uk/statistics/statistical-work-areas/diagnostic-imaging-dataset/diagnostic-imaging-dataset-2018-19-data/

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:

Appendix I

List of publications that illustrate how deletion of this exemption would impact choice of available diagnostic equipment for EU hospitals and clinics:

Title	Date of Publication	Author (s)	Position	Published By	URL
Synergies in ultrasound	Jan 2017	Dr Dirk-André Clevert	Head of Interdisciplinary Ultrasound Center, Department of Radiology, University Hospital, Munich	Customer story ©2017 Koninklijke Philips N.V.	http://incenter.medical.philips.com/doclib/enc/14747777/Philips_Affiniti_Ultrasound_Customer_Story_Synergies_in_Ultrasound_Cleve...pdf%3ffunc%3ddoc.Fetch%26nodeid%3d14747777
Clinical effectiveness of PureWave technology in imaging obese patients - Results of a six-site study	Oct 2012	University of Alabama Hospital and the Kirklin Clinic; Birmingham, Alabama, USA		Case Studies © 2012 Koninklijke Philips Electronics N.V.	http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577260/593280/593786/C5-PureWave-TDP-Study-Whitepaper.pdf%3fnodeid%3d9724460%26vernum%3d-2
		University of Texas M.D. Anderson Cancer Center; Houston, Texas, USA			
		Cliniques Universitaires Saint Luc UCL; Brussels, Belgium			
		University of Colorado; Denver, Colorado, USA			
		St. Paul's Hospital; Vancouver, British Columbia, Canada			
		Freeman Hospital; Newcastle Upon Tyne, UK			
New trends in liver ultrasound	Apr 2012	Clevert D.-A	Interdisciplinary Ultrasound-Center, Department of Clinical Radiology, University of Munich-Grosshadern, Germany	© 2012 Koninklijke Philips Electronics N.V.	
		Helck A.			
		Lee C.			
		Reiser M.F.			
		Lerchenberger M.	Department of Surgery, University of Munich-Grosshadern Campus, Munich, Germany		
Point shear wave elastography method for assessing liverstiffness	Apr 2014	Giovanna Ferraioli	Department of Infectious Diseases,Fondazione IRCCS Policlinico San Matteo, Medical School Universityof Pavia, 27100 Pavia, Italy	World Journal of Gastroenterology	https://www.ncbi.nlm.nih.gov/pubmed/24782633
		Raffaella Lissandrin			
		Mabel Zicchetti			
		Gaetano Filice			
		Carlo Filice			
		Barbara Dal Bello	Department of Pathology, Fondazione IRCCS Policlinico San Matteo, 27100 Pavia, Italy		
		Carmine Tinelli	Clinical Epidemiology and Biometric Unit, Fondazione IRCCS Policlinico San Matteo, 27100 Pavia, Italy		

Title	Date of Publication	Author (s)	Position	Published By	URL
Noninvasive liver fibrosis assessment	Jul 2014	Richard G. Barr, MD, PhD, FACR	Diagnostic Radiology, Hitchcock Imaging, Youngstown, OH	© 2014 Koninklijke Philips N.V.	https://www.usa.philips.com/b-dam/b2bhc/us/topics/shearwave/LiverAssessment_DrBarr_WhitePaper_V4_LR.pdf
Ultrasound solution for the technically difficult patient	Dec 2007	Cathy Fix, RDMS	Ultrasound Supervisor, St. Paul's Hospital Clinical Instructor, Department of UBC in Radiology	© 2007 Koninklijke Philips Electronics N.V.	https://www.usa.philips.com/c-dam/b2bhc/us/feature-details/purewave/45229112881_EPIQ_PureWave_DataSheet_FNL_lr.pdf
An ultrasound solution for challenging patients	Dec 2007	Courtney Nelms, BS, RVT, RDMS, FSVU	Southside Vascular Laboratory Supervisor and Technical Director Vascular & Transplant Specialists Virginia	© 2007 Koninklijke Philips Electronics N.V.	
Combining modalities for more confident diagnoses	Sep 2013	Dr. Dirk-André Clevert	Head of Interdisciplinary Ultrasound Center, Department of Radiology, University Hospital, Munich	© 2013 Koninklijke Philips N.V.	http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577243/577244/582196/582197/Combining_modalities.pdf%3fnodeid%3d11799952%26vernum%3d-2
EPIQ Evolution 3.0	Feb 2017	Philips Marketing		© 2017 Koninklijke Philips N.V.	

Appendix II

List of publications that illustrate how the development of new innovative products can improve health of EU patients:

Title	Date of Publication	Author (s)	Position	Publisher	URL
Assessment of carotid body tumor using the eL18-4 transducer with MicroFlow Imaging	May 2018	R Challis	Vascular Technologist, Regional Vascular Services, North East of England	Case Study ©2018 Koninklijke Philips N.V.	https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-carotid.pdf
		V Cooke	Vascular Technologist, Regional Vascular Services, North East of England		
		B Stenberg, PhD	Consultant Sonographer, Radiology, Newcastle upon Tyne		
		M McNeill, MD	Consultant Radiologist, Radiology, Newcastle upon Tyne		
The eL18-4 PureWave linear array in the detection of pharyngeal space neck pathology	Dec 2017	Dr. Andrew McQueen	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-el18-4-neckpathology.pdf
		Dr. Ben Stenberg	Consultant Sonographer		
		Dr. Andrew McNeill	Consultant Radiologist		
		Radiology, Freeman Hospital	Newcastle upon Tyne NHS Hospitals Trust, United Kingdom		
The eL18-4 PureWave linear array with MicroFlow Imaging in the assessment of focal cortical infarction in a transplanted kidney	Nov 2017	MAF McNeill, MBBS, FRCR	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	https://www.usa.philips.com/c-dam/b2bhc/master/sandbox/marketing-catalog/ultrasound/general-imaging/pdfs/case-study-freeman.pdf
		B Stenberg, PhD	Consultant Sonographer		
		Freeman Hospital	Newcastle upon Tyne, United Kingdom		
The eL18-4 PureWave linear array with MicroFlow Imaging (MFI) in diagnosis of palpable breast masses	Dec 2017	Lynwood W. Hammers, DO	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-breast-masses.pdf
		Hammers Healthcare Imaging, LLC	New Haven, CT		
The eL18-4 PureWave linear array with MicroFlow Imaging (MFI) in diagnosis of breast abnormalities	Dec 2017	Lynwood W. Hammers, DO	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-microflow-imaging-breast-abnormalities.pdf
		Hammers Healthcare Imaging, LLC	New Haven, CT		
	Jan 2018	Lynwood W. Hammers, DO	Consultant Radiologist		

Title	Date of Publication	Author (s)	Position	Publisher	URL
The eL18-4 PureWave linear array with MicroFlow Imaging (MFI) in diagnosis of muscles, tendons, ligaments, nerves, soft issue, and interventional procedures		Hammers Healthcare Imaging, LLC	New Haven, CT	Case Study ©2017 Koninklijke Philips N.V.	https://www.usa.philips.com/c-dam/b2bhc/master/sandbox/marketing-catalog/ultrasound/general-imaging/pdfs/case-study-musculoskeletal.pdf
The eL18-4 Pure Wave linear array with MicroFlow Imaging (MFI) in diagnosis of thyroid, lymph nodes, and salivary glands in the evaluation of neck pain	Jan 2018	Lynwood W. Hammers, DO	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	
		Hammers Healthcare Imaging, LLC	New Haven, CT		
The eL18-4 Pure Wave linear array with MicroFlow Imaging (MFI) in diagnosis of thyroid cancer, lymph node metastasis, and salivary gland abnormalities	Dec 2017	Lynwood W. Hammers, DO	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	
		Hammers Healthcare Imaging, LLC	New Haven, CT		
The eL18-4 PureWave linear array with MicroFlow Imaging (MFI) in diagnosis of thyroid cancer and lymph node metastasis both pre- and post-op	Dec 2017	Lynwood W. Hammers, DO	Consultant Radiologist	Case Study ©2017 Koninklijke Philips N.V.	
		Hammers Healthcare Imaging, LLC	New Haven, CT		
Evaluating vascular flow in suspected placenta accreta	Jun 2018	Luis F. Goncalves, MD	Phoenix Children's Hospital Phoenix, AZ	Case Study ©2018 Koninklijke Philips N.V.	https://www.philips.com/c-dam/b2bhc/master/landing-pages/epiq/pdfs/case-study/case-study-placenta-accreta.pdf
Realizing dramatic improvements in the efficiency, sensitivity and bandwidth of ultrasound transducers	2006	Jie Chen, PhD	Corporate Staff - Philips	© 2006 Koninklijke Philips Electronics N.V.	http://incenter.medical.philips.com/doclib/enc/fetch/2000/4504/577242/577260/593280/593431/Philips_PureWave_crystal_technology.pdf%3fnodeid%3d1659121%26vernum%3d-2
		Rajesh Panda, PhD	Transducer Technologies Manager - Philips		
		Bernie Savord, MS	Philips Principal Scientist - Philips		
eL18-4 PureWave linear array	Sep 2017	Philips Marketing		© 2017 Koninklijke Philips N.V.	
EPIQ Evolution 4.0	Sep 2017	Philips Marketing		© 2017 Koninklijke Philips N.V.	

Title	Date of Publication	Author (s)	Position	Publisher	URL
The ultimate ultrasound solution for breast assessment	Mar 2018	Philips Marketing		©2018 Koninklijke Philips N.V.	