COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

Exemption Request Form

Date of submission: _____

1. Name and contact details

1) Name and contact details of applicant:

Company:	COCIR	Tel.:	+32 (0) 2 706 89 66
Name:	Riccardo Corridori	E-Mail:	corridori@cocir.org
Function:	Senior Manager, Environmental, Health and Safety Affairs	Address:	Diamant Building - 80 Bd A. Reyers - 1030 BRUSSELS, BELGIUM

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
- ☒ 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: 27

Proposed or existing wording:

Lead in

- **solders,**
- **termination coatings of electrical and electronic components and printed circuit boards,**
- **connections of electrical wires, shields and enclosed connectors,**

which are used in- magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment.

Duration where applicable: **Maximum validity period of seven years**

☐ Other: _____

3. Summary of the exemption request / revocation request

MRI is a 3D medical imaging technique used to examine soft tissue. It relies on a very powerful electromagnet and images are sensitive to any magnetic materials that are used in circuitry that is inside and close to the electromagnet. As a result, special non-magnetic components must be used. Substitution work has been underway since 2011 but is not yet complete and so more time is needed before MRI coils and circuits can be constructed with lead-free solders without negatively affecting image quality or EU healthcare provision.

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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 devices, specifically MRI, including CT/MTI and PET/MRI and other equipment designed to be used inside or close to the MRI magnet.

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: _____

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: Additive in soft solder used to make electrical connections between electronic components and printed circuit boards

4. Content of substance in homogeneous material (%weight): Typically 37% by weight

5. Amount of substance entering the EU market annually through application for which the exemption is requested: ca. 200kg per year
Please supply information and calculations to support stated figure.
No accurate total is available. 100kg was estimated by MRI manufacturers in 2006 and previously reported in reference 1. COCIR has assumed that the market size of MRI coils and circuits using lead solder has increased by 2X since 2006

6. Name of material/component: Solder alloys containing tin and lead

7. Environmental Assessment: _____
LCA: ☒ Yes, see section 6 (A) “Impact on EU healthcare without this exemption” for a qualitative comparison of the overall impacts. A quantitative comparison is not possible as healthcare impacts are not quantifiable with any accuracy, although are undoubtedly, very significant.
☐ 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?

Several medical imaging and analytical techniques utilise very powerful magnets including Magnetic Resonance Imaging (MRI) devices, which typically utilise magnets with field strengths of 1.5 or 3 Tesla. To put this in context, the electromagnet of a scrapyard crane typically has to generate a field strength of 1 Tesla to lift a car. In some cases, MRI devices can utilise very powerful superconducting magnets with field strengths of up to 8 Tesla and higher. Again, to put this in context, CERN's Large Hadron Collider, the world's most powerful particle accelerator, utilises electromagnets with the main dipoles generating 8.3 Tesla magnetic fields (100,000 times more powerful than the Earth's magnetic field).

MRI is a medical technique used to diagnose conditions associated with soft tissue and internal organs such as for detecting tumours, blockages in blood vessels and damage to internal organs. MRI uses the very powerful magnetic field of a large very powerful circular electromagnet in which the patient is placed. Electrical circuits that are located close to and within the magnetic field must use non-magnetic components where possible to avoid degradation of the MRI image. This is especially important for the electronic circuits that are within the MRI magnet or are electrically connected to these circuits nearby as any magnetic materials in these would affect the magnetic field and as a result distort the MRI image making diagnosis difficult or impossible. To obtain the very powerful magnetic field, a large superconducting coil has to be used and these must be cooled in liquid helium. Consequently, the electrical circuitry close to the superconducting coil must be both non-magnetic and able to operate reliably for at least 15 years and ideally for 25 years at low temperature and maintain functionality while exposed to severe vibration that occurs when the MRI is used.

When a patient is examined by MRI they are exposed to a very powerful magnetic field. "Radio Frequency (RF) send and receive coils" are located around the patient and inside the magnetic field. These coils transmit RF signals which excite magnetised protons in the soft tissue of the patient and the protons then emit characteristic signals that are received and measured by these coils. One of the essential characteristics of the coils and the electronic circuitry that is connected to each coil is that these must be non-magnetic because any magnetic materials degrade the weak RF signals resulting in distorted MRI images. Research has shown that magnetic metals such as nickel, even in very small electronic components, can have a magnetic susceptibility that is

sufficient to degrade the image quality reducing the ability to detect small features such as tumours or blood clots.

The types of electronic components used in MRI are essentially the same as are used in other electrical equipment such as capacitors, inductors and resistors, but special "non-magnetic" versions need to be used. The most common termination coating used for standard electrical components in most electrical products is tin electroplated over a nickel plated barrier layer on a copper or copper alloy lead-frame. Nickel barriers prevent the inter-diffusion between the thin tin coating and copper substrate during storage where tin and copper would react to form an unsolderable copper-tin intermetallic phase. However, nickel is strongly ferromagnetic and so usually cannot be used within the region of the RF coils or close to the electromagnet.

Components used for MRI within the magnetic field or connected to send and receive coils need to be soldered to create the electronic circuits and so components having nickel-free solderable coatings need to be used. These non-magnetic components are manufactured specifically for MRI and similar applications. The choice of terminal materials is very limited as the metal used for the outer surface must be wetted by solder easily and quickly to form a reliable bond, but must not degrade during storage before use so that soldering becomes impossible.

Several related applications require this exemption:

- Lead in solders used for making connections to non-magnetic components in separately supplied MRI radio frequency (RF) send and receive coils that are used with MRI for imaging specific parts of patients' bodies
- Lead in solders used for making connections to non-magnetic components in body and posterior coils that are integral to MRI
- Lead in the solderable coatings of non-magnetic electronic components used in the superconducting magnet assembly and ancillary equipment

A large variety of RF send and receive coil designs are used with MRI which are designed for imaging a wide variety of body parts; there are for example, coils designed for the body, for arms, legs, head, knee, wrist, breast, etc. One manufacturer currently supplies over 130 different types of coil.

The current range of coils will also be needed as replacement spare parts for MRI that are placed on the market while exemption 27 is in effect. These replacement spare parts would, however, be excluded from RoHS by Article 4.4(f). Nevertheless hospitals will also want to buy additional new coils to use with their MRI, which are not replacements, and so these coils would need this exemption.

Non-magnetic components of MRI are usually soldered to flexible PCBs by hand with soldering irons. An example of an assembled PCB is shown in Figure 1 below. All of these components are non-magnetic.

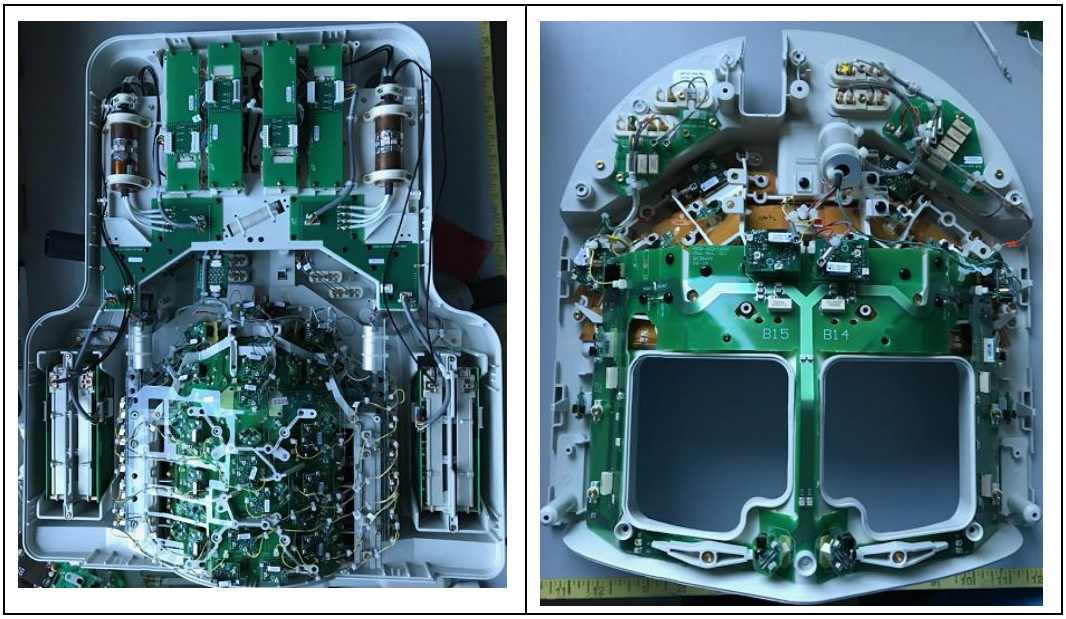

Figure 1. Non-magnetic circuitry of 32 channel digital head coil

It is sometimes possible to use magnetic components, but only under certain specific circumstances:

- Some MRI components are fairly large (see Figure 1 above) and so the magnetic versions would contain large amounts of nickel, which would be unacceptable as these would distort images. Versions of these components containing very small amounts of magnetic metals such as nickel may be acceptable if they do not cause image distortion.
- If many very similar circuits having identical magnetic fields are arranged around the patient cavity, it is possible to design these so that the impact of the magnetic components on the image quality is negligible. This is not possible with most MRI circuits and so they must use non-magnetic components. For example, if there may be only one of a type of module that is located at one side of the patient.

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

i. Rapidly produces a strong permanent low electrical resistance bond between non-magnetic components and circuit boards

ii. 100% of bonds in each MRI must be reliable and last at least 25 years. If located close to the electromagnet, they must also withstand operation at low temperatures.

iii. Solderable coatings of components must remain solderable during storage before use, which can be several years.

iv. The materials used must not distort MRI images – otherwise this could be to the detriment of the diagnosis and so the health of the patient who is the subject of the MRI

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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.)

Coils are recycled at end of life but MRI are usually returned to manufacturers for refurbishment

2) Please indicate where relevant:

☒ Article is collected and sent without dismantling for recycling - coils

☒ Article is collected and completely refurbished for reuse – many MRI

☒ Article is collected and dismantled:

- ☒ The following parts are refurbished for use as spare parts: In principal any part could be reused
- ☒ The following parts are subsequently recycled: Parts that cannot be reused, e.g. because they are damaged, are 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 — Coils that are refurbished are not waste

☐ In articles which are recycled — 200kg

☐ 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

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Bonding of MRI coils

Alternative design by replacing discrete components with integrated components

One approach that is being used by manufacturers is to redesign coils using flexible laminate without discrete components and so avoiding the need for soldering. This possible approach is to incorporate passive components such as capacitors into flexible laminates by screen printing thick-film dielectrics. This avoids the reliability concern over soldering to discrete non-magnetic components as the capacitors are screen or stencil-printed directly onto the circuitry.

When RoHS included medical devices in scope in 2014, it was then not possible to use lead-free solders because testing showed that lead-free versions were unreliable[1] and so exemption 27 was granted. Since then manufacturers have carried out research to replace lead solders and only recently have been able to produce a small number of coil designs without lead solders by not using discrete components. This research showed that it is not possible to simply replace discrete components with printed dielectric materials because the dimensions and electrical characteristics of printed dielectrics are different to discrete capacitors. Therefore every coil would need to be redesigned to develop “lead-free” versions. To redesign one type

[1] See COCIRs exemption request submitted 2012, http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf .

of coil, test for reliability, carry out clinical trials and gain Notified Body approval requires very significant effort from trained engineers.

As stated above in section 4, each MRI manufacturer offers hospitals a very large number of different types of coil which are required for imaging different parts of the body. The number of skilled engineers globally who are able to redesign coils, carry out testing, clinical trials and apply for Notified Body approval very limited. Each MRI manufacturer has a a limited number and can increase the number only by poaching from competitors, who would then have fewer resources for substitution research or train more employees, but this will take many years, probably more than 10 and these new employees will not have the same experience as existing engineers. MRI engineers are also required to develop new products and solve manufacturing issues when they arise as well as work on substitution so that more effort on substitution can only be made at the detriment of new medical diagnosis developments and this would have a negative impact on healthcare in the EU as explained below.

Impact on EU healthcare without this exemption

The practical inability of manufacturers to redesign all RF coils and other parts of MRI to replace lead solders for the reasons explained above would mean that EU hospitals cannot buy all of the types of coils that they will need after exemption expiry. As a result, medical staff will not be able diagnose illness of their patients using MRI which is the best and often the only diagnostic technique available. If tumours, blood clots, the causes of strokes, etc. cannot be diagnosed using MRI, patients could at worst die and, at best, their treatment would be severely delayed. This is one of the main justifications for this exemption, but other reasons as explained below should also be considered.

Delaying new product innovations and development

Diverting MRI engineers away from new product development to changing existing coil designs would negatively affect future health of EU citizens. This is because the only reason for development of new medical devices is to produce new designs with superior diagnostic capability. In the example of MRI, recent new innovations have been to develop digital coils to replace analogue coil designs. One manufacturer claims that digital coils have 40% better signal to noise ratio than analogue designs[2]. 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 and this improves the likelihood of recovery and recovery is 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, is not possible as the positive and negative impacts of each scenario are not directly comparable with each other and some

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

impacts are for hypothetical future developments and so cannot be quantified. However, an illustrative comparative LCA can show which scenario is preferable overall as is shown below:

Impact	New medical devices	Replace lead
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[3]	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[4]
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[5].	No impact, unless the substitute is less reliable then patient health would be negatively impacted
End of life	All medical devices are collected and recycled as required by the WEEE directive. As medical devices such as MRI 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[3].	Recycling of coils is carried out for metals recovery using smelters. This process is designed to accept a wide variety of materials (apart from circuit boards) including lead which is safely recovered with emissions very closely controlled to comply with the EU Industrial Emissions Directive. Therefore the comparative impact of recycling coils with lead or without lead is likely to be very small.

[3] 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"

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

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

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 coils, it appears that new medical device development would give a significant overall health and environmental benefit compared to lead substitution in existing medical products. This result is probably unique to medical devices as new products are designed to save lives and cure illnesses.

Other MRI circuits within the magnetic field

Substitute solders

As explained in COCIR's 2011 exemption request, tests carried out by MRI manufacturers using lead-free solders with non-magnetic components gave poor and unsatisfactory reliability[1]. Further tests of MRI circuits using lead-free solders at low temperature also gave poor reliability. Since 2011 some new non-magnetic components have been developed (mainly passive components) which are claimed to be suitable for lead-free soldering using SnAgCu solders. However, not all of the components incorporated on printed circuit boards that are used close to the MRI magnet are available as lead-free solderable types. It will be possible to switch to lead-free solders only when 100% of non-magnetic components used in MRI are suitable for lead-free soldering and this is not currently possible. Also, it is usually not feasible to solder some of the components with lead-free solders and then others with lead-solders (to reduce the amount of lead used) when the preferred soldering method is surface mount where all components are bonded simultaneously using one solder paste that is stencil printed onto the unpopulated PCB before attaching components.

Another issue with solder bonds in circuits close to the electromagnet is that these are used in exceptionally hostile conditions. MRI circuits close to the magnet suffer from severe vibration as well as being very cold when close to the liquid helium cooling circuit, which for many will be within 1 metre of the isocentre of the electromagnet. A difficulty that manufacturers of MRI have therefore is that not all components can be obtained as types of non-magnetic components that are suitable for lead-free soldering. Note that an MRI is RoHS compliant without exemption 27 only when 100% of solder bonds are lead-free. The other issue is that when a prototype MRI can be made using non-magnetic components and lead-free solders, it

will need extensive reliability testing. Manufacturers report that after initial tests, premature solder bond failures occur.

Physical connections

Several types of physical connection are used in electrical equipment such as crimp connectors and plugs and sockets. These however can be unreliable in long lifetime equipment, especially when exposed to severe vibration as occurs in MRI scanners. Vibration causes small sideways movements of the two parts of physical connections and cause failure due to a phenomenon called fretting. This is a common problem with tin plated connections but can occur with any metal including gold plated connectors[6] when the sideways movement wears away the coating metal layer to expose base metal substrate that oxidises as the sideways movement abrades off air-formed oxide to expose clean metal which then rapidly re-oxidises. Gradually, the amount of oxide builds up until there is sufficient between the metal parts to increase electrical resistance. This oxide build up then causes resistance heating which accelerates oxidation and eventually an open circuit is created.

Also, physical connections often occupy too much space to be used on high density printed circuit boards so are technically impractical.

Conducting adhesives

Bonds made with conducting adhesives can be formed at lower temperatures, but have significant reliability issues. These are very uncommon as an alternative to solders because their reliability can be poor due to the contact resistance increasing over time resulting from surface oxidation of terminal surfaces. This can occur even with silver or gold coated copper pads because the copper slowly diffuses into the silver or gold and oxidises when it reaches the surface. Note that nickel barrier coatings cannot be used to retard copper migration as these are magnetic. The conductor particles in some types of adhesive can also oxidize or corrode. The conductors used in these materials are usually silver or other precious metals, but these can form a galvanic cell with the substrate copper accelerating its oxidation. Vibration is another cause of poor reliability of conducting adhesives by delaminating the adhesive bonds and MRI circuits suffer from very severe vibration due to the RF fields used for imaging. Conducting adhesives are not specified for use at very low temperatures, mainly because they become very brittle, but many of the MRI circuits are close to the liquid helium cooling circuit so can be at very low temperatures for very long periods.

[6] http://www.sciencedirect.com/science/article/pii/0043164881901927

Brazing and welding

Brazing typically occurs at about 350°C and welding at over 1000°C. These temperatures will destroy the polymer insulation of flexible circuit laminates and components so cannot be used.

The use of high melting point solders is also not a technically viable option. Although solders containing >85% of lead are covered by a RoHS exemption, their melting temperatures of about 300°C is also too hot as this will damage polymer insulation of circuit laminates and components

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

Data was included in COCIR's original request for this exemption submitted in 2011[7]. This is still valid and these reliability issues have not been resolved.

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.

Coils

A method to avoid lead solders in coils has recently been developed by replacing discrete components with printed components. However as explained in section 6, even if all available engineers were involved, it is expected to take at least 10 years to convert all of the types of circuit and coil.

MRI circuits

Manufacturers of discrete components such as capacitors and resistors are developing non-magnetic components that can be soldered using lead-free solders. These are being used in MRI, but for the reasons explained in section 6, it is not yet possible to use lead-free solders for this application.

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

Coils

Redesign of each type of coil is not straightforward and will take many months. Once this stage is complete, prototypes can be constructed and tested to determine if the performance is

[7] http://rohs.exemptions.oeko.info/fileadmin/user_upload/Rohs_V/Request_9/9_COCIR_-_Exemption_request_-_Lead_solder_magnetic_field.pdf

correct and that the design will be reliable. Once this is complete, clinical trials can be carried out. These are needed to obtain data for gaining approval under the Medical Devices Regulation by a Notified Body. The timescale for one coil is shown below:

Stage	Time required
Redesign	7 months
Prototype reliability and performance testing	3 months
Clinical trials	1.5 months
Notified body approval	1.5 months
Total	13 months

Due to limitations on the number of skilled engineers available globally, the above activities cannot be carried out in parallel for a large number of coil designs and so the total elapsed time required for over 100 coil designs will be expected to take several decades to complete. This is due to the limited number of suitable available engineers, the high number of coils needing redesign and ultimately the availability of manufacturer parts (non-magnetic components) that do not rely on this exemption. Many of the parts currently used rely on this exemption and the manufacturers of these parts are not currently able to provide substitutes at present and they have stated that they will not be able to provide lead-free substitutes until well after July 2021.

MRI circuits

Research into substitution of lead has been carried out since 2011 and is continuing. The increasing availability of non-magnetic components that are suitable for lead-free solders over the last few years has helped but more work is needed to resolve technical problems with premature bond failure and to be assured that reliability will be at least the same as current MRI.

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
☐ Proposal inclusion Annex XIV
☐ Annex XIV

☐ Restriction

☐ Annex XVII
☐ Registry of intentions

☒ Registration - lead has been registered – see https://ila-reach.org/our-substances/lead-metal/ and 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: Depending on type of circuit, either for reliability uncertainty reasons or for technical and EU citizen's health reasons, as explained above.

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

☒ Yes.

☒ Design changes: For coils but not before 2021 as explained in section 6
☐ Other materials:
☐ Other substance:

☒ No.

Justification: Poor and uncertain reliability as not all electronic components used are yet available as non-magnetic and lead-free solderable versions

3. Give details on the reliability of substitutes (technical data + information): Please see referance 1

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
    1) Environmental impacts: Please see section 6 summary LCA
    2) Health impacts: Please see section 6 summary LCA
    3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof? Yes, but this can be demonstrated qualitatively only – see section 6
Please provide third-party verified assessment on this:

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Alternative designs are available only from MRI manufacturers
b) Have you encountered problems with the availability? Describe: Not applicable
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? See section 6

(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 Significant R&D and redesign costs. This expenditure would be made instead of new product development. This would negatively affect future healthcare as new innovative products potentially give superior diagnosis and treatment whereas replacing lead solder by lead-free will not improve the performance of the modified MRI.

☐ Increase in overhead

☒ Possible social impacts within the EU - Without this exemption, very few types of RF coil (as explained in section 6) would be available in the EU. EU citizens' health would be negatively affected as they could not be effectively treated without these coils or the full range of types of MRI equipment. MRI have different characteristics which makes each model suitable for specific uses. For example, MRI need to have strong magnetic field gradients and high slew rates[8] depends if cardiac or brain imaging is anticipated. Only some

[8] The slew rate of an MRI magnet is a measure of how quickly the magnetic field can be ramped on or off.

of the MRI on the EU market have this capability. If manufacturers were forced to substitute lead solders without time for reliability testing, two scenarios could result:

a. They would not gain Notified Body approval so could not be sold in the EU
b. If they were approved, but reliability is found in the future to be inferior, unexpected failures would cause delays in medical treatment with resultant negative health impacts

☒ Possible social impacts external to the EU – Very limited as other countries do not restrict lead in medical devices. However, if a manufacturer redesigns their MRI to use lead-free solders, these are sold globally and then proves to be less reliable, this would negatively impact healthcare in non-EU countries as well as in the EU.

☐ 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:

_____

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:

_____