Exemption Renewal Form - Exemption 11 Annex IV

Date of submission: **02 January 2020**

Attached documentation:

COCIR - Confidential quantity calculation Renewal exemption 11

1. Name and contact details

1) Name and contact details of applicant

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 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: **11 of Annex IV**

Proposed wording: **Lead and its alloys as a superconductor and thermal conductor in MRI**

Duration where applicable: **Maximum validity period**

☐ Other: _____

3. Summary of the exemption request / revocation request

Lead and its alloys are used to make superconducting and thermal bonds to superconducting electromagnet coils of medical Magnetic Resonance Imaging (MRI) scanners. Superconducting materials must be used to achieve the very powerful magnetic fields needed to obtain clear MRI images. The bonding material that contains lead must be a superconductor as otherwise, the large current used to generate the powerful magnetic field would cause enough heat to raise the electromagnet coil's temperature above the superconducting critical temperature; rapid heating would occur and the MRI would not function. Very few metals suitable for making bonds are superconductors at the temperature required for the magnet coils to be a superconductor and only lead and certain of its alloys meet all of the essential requirements which include an ability to be formed into a reliable bond.

This exemption needs to be renewed for the foreseeable future to allow new MRI to be sold in the EU as no substitute materials or designs exist with proven reliability for decades at low temperatures.

MRI manufacturers have assumed that exemption 11 is the applicable exemption for superconducting and thermal bonds made with lead or lead alloys in MRI. However, lead as a thermal conductor (used in cyrocoolers, cold heads, i.e. cryorefridgeration components) has been assumed to be covered by exemption 29 so does not also need to be included in exemption 11. COCIR has learned that some manufacturers, especially NMR manufacturers, rely on exemption 12[1] for lead in superconducting bonds to superconducting electromagnet coils used in both MRI and NMR. Only one of these exemptions would appear to be needed to cover superconducting and thermal bonds as described in this renewal request.

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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: Magnetic Resonance Imaging (MRI) medical device including MRI/CT and MRI/PET.

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

[1] Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors, expires 21 June 2021.

☐ 1
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☐ 11

b. Please specify if application is in use in other categories to which the exemption request does not refer: To COCIR knowledge, Category 9 applications such as NMR (but NMR are covered by exemption 12).

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: Superconducting electrical connection to and within superconducting magnet coils

4. Content of substance in homogeneous material (%weight):
ca. 40 - 99.9% lead

5. Amount of substance entering the EU market annually through application for which the exemption is requested: ca. 1 tonne lead placed annually on EU market
Please supply information and calculations to support stated figure.
Sales of MRI in the EU in 2016 were 1013 units (COCIR market intelligence data). COCIR believes that average EU sales are about 900 units per year. The amount of lead used per MRI varies depending on manufacturer and MRI design. The estimated average used here is 1kg per MRI.

6. Name of material/component: lead metal and lead-bismuth alloys are both used

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?

Magnetic Resonance Imaging (MRI) is used to obtain three-dimensional images of soft tissue and organs in human patients. MRI uses a very powerful circular electromagnet into which the patient is placed to expose them to a very powerful magnetic field. "Radio Frequency (RF) send and receive coils" are located around the patient and inside the magnetic field and these transmit RF signals which excite magnetised protons in soft tissue and organs of the patient and the protons then emit characteristic signals that are received and measured by these coils and this is used to generate the image.

The circular electromagnet has to be very powerful to obtain detailed images and modern MRI use magnets of 0.3 to 7 Tesla and higher, depending on the type of diagnostic techniques that are used and image quality required, although 1.5 and 3 Tesla magnets are the most commonly used clinical types. Image quality improves as the field strength increases.

The only way that high power MRI electromagnets can be made is to use superconductors for the electromagnet coil. The magnetic field strength is proportional to current and number of turns of superconducting wire so the powerful magnetic field is achieved by passing a high current, typically of 400 to 800 amps (typical for 1.5 and 3 Tesla MRI) through many kilometres of superconducting wire. At ambient temperature, all metals have a small electrical resistance so that passing this very large current will cause heating of the wire and its connecting bonds raising their temperature significantly and potentially this heat could destroy insulating materials or even melt the metal. To avoid resistance heating, MRI use superconducting wire and bonding materials which have zero electrical resistance. It is important that the bonding material is a superconductor because passage of 800 amps through a material with even a small electrical resistance will cause at least enough heat to warm the superconducting coil to above the critical superconductor temperature so that it is no longer a superconductor. The increased temperature would also boil away the liquid helium which would be lost. It is currently not possible to achieve the high magnetic field strength (>0.4Tesla) required in an MRI with an electromagnet coil at ambient temperature or without superconducting materials at very low temperature. This has been the case now for several decades.

MRI magnets overcome this issue of resistance heating by using superconducting coils that have zero electrical resistance at very low temperatures and so the passage of high current generates no heat. The types of superconductors that are used for large reliable MRI magnets are niobium alloys and usually niobium-titanium alloy is used, although niobium-tin can also be used. Niobium-titanium wire is fairly brittle, especially at low temperatures, so it needs to be supported by embedding it into copper which acts as a physical support. Niobium alloys are superconductors only a temperatures below 9.4K so are either immersed in liquid helium which has a boiling temperature of 4.2K or they are in good thermal communication through thermally conducting bonds with a cooling system that operates at ~4..2K. Modern MRI designs are very efficient so that there is no steady loss of helium (so long as power and water cooling is provided for the cyrorefridgeration system) while the MRI is in normal use and only small amounts are vented during maintenance, although some helium can be lost if a fault occurs or if the magnet needs to be switched off in an emergency. This is important because the global helium supply is very limited, global shortages have occurred and MRI cannot be used without it.

The superconducting coil has to be electrically connected to the power supply to be energised. The bonding material that is used must not generate heat due to resistance heating when the current is passed, because this would raise the temperature of the bonding material and the connected superconductor coil so that the coil is no longer superconducting. Heating of the bonding material is avoided by using bonding materials that are also superconductors at 4.2K so that no heat is generated at the bonds to the superconducting coil. Previously, an alloy containing lead and cadmium was used (Woods alloy), but cadmium-free alloys can now be used and lead metal and lead-bismuth alloy have been found to be the most suitable superconductors for bonding. Each MRI manufacturer has their own proprietary designs so there is variation in the bonding materials that are most suitable and used.

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

The material used to make bonds to MRI coils must have all of the following properties:

- Superconductor at temperature of MRI coil (at 4.2K) and ideally at temperatures higher than 4.2K
- Must be a superconductor when passing the required current to MRI coil. All superconductors cease to be superconducting when passing currents

above the critical current density value of the material, so they should have a relatively high critical current.

- Must be a superconductor when exposed to intense magnetic field from MRI coil. All superconductors cease to be superconducting when exposed to intense magnetic fields above critical field strength values, so high critical field strength values are required.
- Must be suitable for making electrical connections between MRI coil and external power supply. This requires:
  - A fairly low melting point (<400°)
  - Not interact with niobium alloy superconductor alloys
  - Have some ductility, including at liquid helium temperature. After bonds are made, these are cooled from ambient to -270°C. As the thermal expansion coefficients of Cu/NbTi and solder will be different, this mismatch induces a significant strain which would cause de-bonding if the solder is not ductile.
  - Resistance to vibration from MRI
  - The material must not create intermetallic phases that are not superconductors at the boundary between copper, NbTi and the bonding material
  - The bond material must be stable in all of its temperature use range

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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.)

Manufacturers try to take back used MRIs from users (hospitals and clinics) to refurbish them. Waste MRIs are collected and properly recycled according to the WEEE Directive with very high recycling rates.

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: Many of the component parts can be reused, but the lead alloy bond to the superconducting coil is always recycled for materials recovery,

☒ The following parts are subsequently recycled: The rest of the MRI including all lead alloy superconducting bonds

☐ 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. In the medical devices sector, refurbishment means a process that restore performances and safety to a level comparable to when the equipment was new. Refurbishment is always performed on used equipment, extending their life, before they equipment is discarded as waste. Used MRIs are discarded as waste, only if refurbishment is not possible due to the old age of the equipment.

☒ In articles which are recycled

It is very difficult to estimate the number of MRI sent to recycling in EU each year as:

- Hospitals do not necessarily contact the manufacturer (MRI are in scope of the WEEE Directive) and sell the MRI directly to recyclers.
- The recycled MRI units are reported under the more general "Category 8" under the WEEE reporting system
- Since 2018 waste Medical Imaging Devices are reported in an even more general category "Large appliances"

☐ 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

Alternative materials and bonding technologies for making electrical connections to superconducting electromagnets are described below. Bonding to alternative electromagnet technologies are also briefly discussed.

Substitute materials to replace lead.

Some metallic elements and their alloys other than lead are superconductors and many non-metallic superconducting materials have been developed. Bonding with metals is more likely to be technically possible than using non-metal conductors so metallic bonding will be considered first. When bonding with lead, the lead melts and flows over the copper/Nb-Ti magnet coil material to make an electrical connection between the lead and NbTi alloy. Lead is a good choice because it does not form intermetallic phases with copper or react with the Nb-Ti. Intermetallic phases, such as tin/copper which would form if tin alloys were used are usually not superconductors. The other important properties of the metal used for bonding are:

- Critical temperature (Tc) above which superconductivity is lost
- Critical field (Hc) above which superconductivity is lost
- Critical current, (Cc) above which superconductivity is lost.

The characteristics of lead and other metals that are superconductors at atmospheric pressure and may be considered for bonding due to having fairly low melting temperature are[2]:

[2] Data from various sources including http://www.superconductors.org/ and "Superconductors", downloaded from https://www.google.co.uk/search?ei=HZBwWruyHIT8gAaF17Qw&q=superconductors+4.2&oq=superconductors+4.2&gs_l=psy-ab.12...2010535.2019011.0.2021383.19.14.0.5.5.0.212.1646.8j5j1.14.0....0...1c.1.64.psy-ab..0.18.1633...0j0i67k1j0i131k1j0i131i67k1j0i10k1j33i160k1.0.fxjZhTBSCSM#

Table 1. Comparison of metallic superconductors

Metal	**Tc (K)**	**Hc (mT)**	**Other limitations**
Lead – bismuth (60% lead) [3]	8.4	1.77 Tesla (1,770 mT) at 4.2K	
Lead	7.19	80.34	Lower Hc than PbBi but fairly high Tc so is suitable in some MRI designs. Hc is higher with addition of Bi, Sb, In, etc.
Tin	3.72	30.55	Reacts with copper to form SnCu intermetallic compounds. Disintegrates at low temperature due to "tin pest" Tc is too low.
Tin- indium (Sn50%In50%)[3]	6.5	640mT, but can drop to <100mT after aging	Most promising substitute, but has a lower Hc than PbBi alloy and also has a lower critical current
Other tin alloys (reference 3)	2.3 to 4.8	40mT	Tc and Hc too low
Indium	3.41	28.15	Tc too low as below boiling temperature of He
Gallium	1.08	5.93	Tc is too low as below boiling temperature of He
Cadmium	0.52	2.8	Toxic, RoHS restricted. Some alloys with cadmium have higher Tc, but Hc is lower than lead alloys)
Zinc	0.86	5.4	Tc too low as below boiling temperature of He
Niobium (for comparison)	9.25	173	Too high melting temperature, much higher than copper

Some metals, such as elemental barium and bismuth are superconductors only at high pressure (or as alloys) and so these elements would be technically impractical. Also, their Tc values are mostly too low at below 4K, which is the boiling point of liquid helium and the temperature at which it is retained in MRI scanners.

Powerful magnetic fields can stop a metal from being a superconductor. Niobium alloys are used for the superconducting coils not only because they have a relatively high Tc for metals and are fairly flexible, but also because they have quite high critical field (Hc) values. The magnetic field of MRI magnets is extremely powerful, reaching many Tesla at the location of the patient. MRIs have to be designed so that the bonds to the coil are in zones of lower field strength so that the material is located where the field is below its critical field value, but high Hc values are essential. This is technically possible for lead and for lead-bismuth in commercial MRI as these have higher Hc and Tc values than other lower melting temperature metals as shown in the table above.

There are no other metals in the periodic table that have relatively low melting temperature (i.e. well below that of copper) and have Tc values sufficiently higher than 4K so that they behave as superconductors when passing a large current and in the magnetic field. Lead and its alloys are therefore the only technically suitable option.

Research has also been carried out with ternary alloys. Sn-In with the addition of third elements have been shown to increase the critical field and critical current values but to values that are much lower than that of lead or lead-bismuth alloy. BiSnIn and SnInSb alloys have been shown to be superior to SnIn, but are very inferior to lead-bismuth[4] and so are unsuitable.

Alternative bonding methods

Research into several alternative bonding methods has been carried, but with only limited success. These are described here.

Cold pressing:

Research[5] has been carried and on a laboratory scale only, low resistivity bonds have been achieved but these are inconsistent and the bonding method is difficult to carry out and requires very hazardous chemicals such as hydrofluoric acid. This type of bonding between two NbTi wires requires that the copper encapsulation is first removed and then that the metal surface is oxide free. Copper can conveniently be dissolved using nitric acid but this leaves an inert coating of niobium oxide as well as residual copper on the superconductor wires that prevent bonding. Alternative methods of removal of copper all leave some oxide coating and residual copper. Removal of oxide has been investigated using hydrofluoric acid based etchants which appears to be effective at oxide removal (but less so for copper) but longer-term testing of bonds shows that results are very variable and superconductivity properties deteriorate. Research at Oxford University showed that oxide and copper at the bond boundary prevent

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[3] Superconducting Joints for Magnet Applications, Susie Speller, downloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications/

[4] Lead-Free Persistent Mode Joints Between NbTi Wires, T J Davies, M Bristow, T Mousavi, A Thomas, M Lakrimi, C R M Grovenor and S C Speller, dowloaded from https://www.stfc.ac.uk/files/superconducting-joints-for-magnet-applications See slide 13.

[5] Review article: Persistent Current Joints between Technological Superconductors, G. Brittles, et.al., Superconductor Science and Technology, Volume 28, Number 9, 2015.

effective bonding[3].

Welding:

Spot welding[3,5] of pairs of niobium alloy wires has been shown to form reasonable metallic bonds. This method causes the metal to melt, disrupts the oxide coating and forms a bond. However, testing of spot welded NbTi wires shows that these have poor (low) critical current values. Techniques to improve the critical current have been investigated and progress is being made so that this may form the basis of a suitable bonding method in the future. However, at present it is technically impractical with commercial MRI electromagnets.

Composite solders:

Bonding using a mixture of lead-free BiInSn solder with a dispersion of strands of NbTi superconductor have been evaluated[4]. This gave superior performance to the BiInSn solder alloy alone, but was very inferior to PbBi alloy solder.

Other bonding methods that are used for electrical circuits are described below although will not be technically practical as the bonds are not superconductors.

> **Physical connection to an electrical conductor**: The metals used for making these connections need to be rigid so that they can impose a bonding force. These types of metals (copper, brass, etc.) will not be superconductors for the reasons explained above and so will generate heat that destroys the superconducting properties of the magnet coil.
>
> **Electrically conducting adhesives**: None are suitable for use at 4K as they will become too brittle. The conductor materials used (copper, silver and gold are most common) are not superconductors so would generate heat that destroys the superconducting properties of the magnet coil.

Non-metallic superconductors

Non-metallic superconductors have been developed which are essentially ceramics and these materials cannot be used for bonding for several reasons. The main reason being because they have too high melting point or decompose without melting. The first so-called "high temperature" superconductor to be developed (yttrium barium copper oxide) melts at over 1000°C so is impractical as a bonding material to copper which melts at 1085°C. To date, bonding of copper NbTi coils to non-metal superconductors as a means of making connections to MRI magnets has not been possible.

Many of the high temperature superconductors are mixed oxides. When heated to very high temperature to bond to copper or other metals, chemical reactions are likely to occur that would change the copper content and the oxygen stoichiometry so that the superconducting properties change or are destroyed[5]. Academic research into bonding to high temperature superconductors is being carried out, but the use of high temperature superconductor bonding to NbTi is not yet technically feasible methods.

Alternative electromagnet designs, materials and bonding

One potential future way to avoid lead may be to change the electromagnet materials so that it does not need to operate at liquid helium temperatures. Research into the use of so-called high temperature superconductors (these can operate in liquid nitrogen) is being carried out but has not yet been successfully used in commercial MRI. This work is described in section 7A. Even if high temperature superconducting electromagnet coils could be made large enough for MRI and be reliable, an electrical connection would still be needed and the preferred material for this with proven reliability is lead. High temperature superconductors are being researched for use in powerful electromagnets for NMR and MRI but it seems likely that these will be used at liquid helium temperatures (to maximise critical field strength) and so lead (alloys) would be the only suitable bonding material.

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

Lead has proven long term reliability whereas there are no lead-free superconductors that meet all of the essential characteristics as listed above in section 4C. No novel substitute bonding materials or MRI designs are yet available for long term reliability testing.

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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.

As explained in section 6, there are no technically practical alternatives to lead or its alloys as a bonding material to low temperature niobium alloy superconducting electromagnets. One potential option to replace the lead connections may be with novel designs of MRI that can operate at higher temperature. There is research being carried out to develop superconductors that can function at temperatures higher than that of liquid helium. Ideally these materials should be superconductors at temperatures above the boiling temperature of liquid nitrogen, which has no limitations on supply. In the last few decades, many new ceramic superconductor materials have been developed and a few have been used in prototype equipment, but these have not yet been used in commercial products, such as medical MRI, because there are still technical challenges to be resolved and extensive testing will be needed to ensure that equipment has long term reliability. However, as described above, MRI and NMR that use high temperature superconductors are likely to be used at liquid helium temperatures to benefit from the superior performance that these materials give (to allow the use of more powerful magnetic fields) and so would still need to use superconducting lead alloys as the bonding material.

Several companies now sell tape with superconductor coatings including BASF[6] who supply tape with yttrium-barium-copper oxide (YBCO) superconductor coating and Fujikura[7] whose tape has a coating of GdBa2Cu3Ox. SEI sell lead-doped BSCCO wire which is used in superconducting electromagnets[8]. YBCO is not ideally suited for powerful electromagnets because it has a low critical current[9] although it has been evaluated as a possible superconducting power cable. Fujikura claim that GdBa2Cu3Ox is suitable for high power electromagnets and based on research carried out at CERN[10], very high magnetic fields may be possible eventually in the future (although this may be at liquid helium temperatures).

As with current MRI, one technical problem is how to make electrical connections to a high temperature superconducting magnet coil. As high currents will need to be passed to achieve powerful magnetic fields, these connections must have very low electrical resistivity. There are no metals that are superconducting at liquid nitrogen temperatures and so the design must rely on very low electrical resistance to avoid excessive heat generation and suitable materials and designs are still the subject of on-going research. High temperature superconductor MRI are however likely to be used at liquid helium temperatures as this would allow much higher magnetic field strengths to be used (than at liquid nitrogen temperatures) which will improve image quality. At this temperature superconducting, only lead-based bonds are suitable.

Siemens and Mitsubishi have developed demonstration electromagnets for MRI, although these are relatively small with coils being suitable for small animals such as a mouse only[11]. Scaling up will entail very significant challenges. MRI experience severe vibration in use whereas ceramics are usually brittle materials and so long term reliability will be a concern.

It could be may be many years before commercial high temperature superconductor based MRI with proven reliability and Medical Device Regulation approval from EU Notified Bodies can be used in the EU. However bonding to the superconductor coils will be required and the same lead and lead alloy bonding methods used for NbTi coils are likely to be needed.

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6 https://www.basf.com/documents/de/about-us/Companies/New_Business_GmbH/business/e-power-management/BASF_HTS_Tape.pdf

7 https://www.fujikura.co.uk/products/energy-and-environment/2g-ybco-high-tempurature-superconductors/

8 https://global-sei.com/super/about_e/index.html

9 As polycrystalline forms, YBCO has a very low critical current values so that when used for MRI, may not superconduct . https://en.wikipedia.org/wiki/Yttrium_barium_copper_oxide

10 https://home.cern/about/updates/2017/09/20-tesla-and-beyond-high-temperature-superconductors

11 https://www.siemens.com/innovation/en/home/pictures-of-the-future/research-and-management/innovations-mri-with-hts.html Also https://www.mdtmag.com/news/2016/05/worlds-first-3-tesla-mri-high-temperature-coils

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

All of the following would be required using either alternative bonding techniques to superconductor MRI electromagnet coils:

- Suitable bonding method that has very low or ideally zero resistivity and perfect thermal conduction properties
- Clinical trials that prove that image quality is equivalent or better than current designs
- Long term reliability is proven over decades
- Approval by a Notified Body for the Medical Devices Regulation

Manufacturers of medical equipment have estimated that work to develop alternative bonding to the currently used types of superconductors with NbTi filaments, if successful (although this cannot be guaranteed), will take about 5 years, although success is not a certainty. Additional time will also be needed, if successful, for reliability testing, clinical trials and gaining approvals adding at least another 5 years, so at least 10 years in total (until 2029 at least).

Other bonding methods described in section 6 have not been found to be technically practical but further research may yield encouraging results in the future, but it is not possible to predict if or when these can be used in commercial MRI and with approval under the Medical Devices Regulation.

Development of high temperature superconducting electromagnet coils of sufficient size for human MRI scanners and suitable bonding will take many years to commercialise and gain approval, but may not avoid the use of superconducting lead alloy bonds.

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 was added June 2018
☐ 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: MRI would not function
2. Can the substance named under 4.(A)1 be substituted?
   ☐ Yes.
   ☐ Design changes:
   ☐ Other materials:
   ☐ Other substance:
   ☒ No.
   Justification: MRI would not function
3. Give details on the reliability of substitutes (technical data + information): No substitutes exist at present
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to – Not applicable as no alternatives exist
   1) Environmental impacts: _____
   2) Health impacts: _____
   3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof? – Not applicable as no alternatives exist
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes: – Not applicable as no alternatives exist at present

a) Describe supply sources for substitutes: None exist

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: – Not applicable as no alternatives exist at present

⇨ 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 – There would be a significant negative impact on the health of EU citizens if this exemption is not renewed. Without this exemption, EU hospitals would not be able to buy new MRI equipment that they need to treat patients. Old equipment becomes increasingly unreliable as it ages so that it will often not be usable. Also, modern designs can provide superior diagnostic capability compared to older models. Therefore there would be a gradual deterioration in overall health of EU citizens without this exemption, although it is not possible to quantify this.

The OECD[12] estimate that about 14 million MRI scans are carried out in the EU annually. Without this exemption, this number will gradually decline as MRI become too old but cannot be replaced. This would result in a growing number of EU patients not being able to be diagnosed using the most suitable technique, which is often MRI. Use of alternatives (if possible) can result in much later diagnosis or misdiagnosis, both resulting in serious health implications and higher healthcare costs. Quantification of the number of patients in the EU affected is difficult but could reach several millions within 5 years as most MRI have a lifetime of 7 – 10 years.

☐ Possible social impacts external to the EU – not affected if exemption is not renewed

☐ Other: _____

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

[12] https://data.oecd.org/healthcare/magnetic-resonance-imaging-mri-exams.htm

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: