Exemption Request Form

Date of submission: 18th December 2019

1. Name and contact details

1) Name and contact details of applicant:

Company:	Megin Oy	Tel.:	+358 9 756 2400 (exch)
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Function:	Product Development Manager	Address:	Siltasaarenkatu 18-20, 00530 Helsinki, Finland

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

Company:	Megin Oy	Tel.:	+358 9 756 2400 (exch)
Name:	Petteri Laine	E-Mail:	Petteri.Laine@megin.fi
Function:	HW development manager	Address:	Siltasaarenkatu 18-20, 00530 Helsinki, Finland

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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: 12 of Annex IV

Existing wording: Lead and cadmium in metallic bonds creating superconducting magnetic circuits in MRI, SQUID, NMR (Nuclear Magnetic Resonance) or FTMS (Fourier Transform Mass Spectrometer) detectors

Duration where applicable: Maximum validity period

☐ Other: _____

3. Summary of the exemption request / revocation request

Superconducting quantum interference devices (SQUIDs) are used to measure extremely weak magnetic fields and are used in applications such as in pre-surgical mapping of brain tumors or epilepsy in medical diagnostics as well as brain research. SQUID detectors require the use of lead containing bonds as part of the superconducting loop which are immersed in liquid helium at 4.2K. The bonds are required to be superconducting to allow the operation of the SQUID detector, as well as to have a high degree of durability to withstand immersion in liquid helium and reliability as it is not possible to build in redundancy into the system to compensate for bond failure.

Potential alternative solutions are either not superconducting at the temperatures required or have reduced reliability either due to the inadequately robust bond formation or potentially due to the formation of tin pest. Alternative technologies which do not rely on lead are being researched by Megin via the macQsimal project; an EU-funded Horizon 2020 research project, however there are a number of technical challenges which will take a number of years to complete in order to demonstrate that Optically-Pumped Magnetometers (OPM) are a viable alternative. It also currently seems unlikely that OPM-based will be able to replace all uses due to their smaller bandwidth and applications that require >100Hz detection will continue to require SQUID based systems.

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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: Superconducting quantum interference device (SQUID) used in magnetoencephalography (MEG)

   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: This application does not refer to NMR, MRI or FTMS detectors which may be covered by other applicant's exemption renewal requests.

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 connections in SQUID detector circuits

4. Content of substance in homogeneous material (%weight): 37-88 %

5. Amount of substance entering the EU market annually through application for which the exemption is requested: 0.068 g

   Please supply information and calculations to support stated figure.

   Each MEG system utilises tin-lead strips and pads, with the lead quantities in each different due to composition and quantities of each connection. Therefore, each connection type is calculated as follows:

   - [redacted]

   As [redacted] systems is estimated to be delivered to the EU annually, the total cumulative amount is [redacted] 0.068 g lead entering the EU market annually.

6. Name of material/component: Tin/lead and lead/indium alloys

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?

Superconducting quantum interference devices (SQUIDs) are used to measure extremely weak magnetic fields. The sensitivities of the present SQUID detectors are of the order of a couple of femtoteslas (10^{-15} T).

Megin utilises SQUID detectors in magnetoencephalography (MEG) systems, i.e. in devices that measure non-invasively brain activity. The magnetic field density generated by the brain activity is in the order of 10^{-13} T when measured outside the head. The magnetic field arises directly from the neurons activating during, for example, physical processes (e.g. moving an arm).

Unlike the other functional imaging techniques (fMRI or PET[1]), where the capability to measure brain activity is based on the relatively slow changes of blood flow in the brain, magnetoencephalography (MEG) and electroencephalography (EEG) measure directly the activation of neurons, offering millisecond-scale time resolution. The MEG signals, however, in comparison with EEG, are not distorted by the skull or tissue surrounding the brain, allowing superior localization capability of the active brain areas. The combination of high temporal and spatial resolution offered by MEG is unique among the functional brain imaging techniques.

Therefore, the SQUID detectors employed in MEG are crucial for medical diagnostics and basic brain research, with the following providing some examples of their existing and future applications:

- MEG is increasingly being used in the pre-surgical mapping of patients with, e.g. brain tumors or epilepsy, due to its high spatial and temporal resolution. It is used for the accurate localization of visual, somatosensory and auditory cortices as well as complex cognitive functions like language processing[2]. A recent study reported that patients who underwent surgery after pre-surgical planning using MEG did not suffer from new somatosensory deficits, indicating the valuable role of such mapping with MEG when planning for surgery[3];
- Similarly, MEG can support oncologists in assessing the impact of a cancer therapy on motor ability, sensory responses, and language processing, helping to form a treatment plan for the patient;
- MEG is used in epilepsy diagnostics. It is able to detect epileptic “spikes” (very fast waves in brain activity) in about 75% of patients whereas EEG

[1] fMRI = functional magnetic resonance imaging, PET = positron emission tomography

detects them in about 60%, but when these are combined, the two technologies can detect almost all spikes[4];

- TBI (traumatic brain injury) can occur in sports, such as American football, traffic accidents, and, for example, in the armed forces. MEG shows great potential in the identification of concussion through abnormal low-frequency activity studies to understand baseline level, the impact of the injury and recovery timelines. Examples of its use have been published[5, 6];
- MEG has been utilised to identify biomarkers of auditory and speech deficits in autism spectrum disorders[7] and Alzheimer's[8].

The technology can also be used in other applications such as for the measurement of muscular activity of heart with magnetocardiography (MCG)[9]. MCG offers advantages over Electrocardiogram (ECG) as described in the paper 'SQUID magnetocardiography; Status and perspectives'[10] which include vector field measurement including all three components in comparison with scalar field surface-restricted measurements and the ability to undertake fetal MCG. Although MCG is not as well established as MEG, it is a growing field with examples in the literature where the technology is proving to be critical for certain applications[11,12].

The MEG system manufactured by Megin Oy uses an array of 306 individual SQUID detectors located in 102 sensor modules to map precisely the pattern of the electromagnetic fields generated by brain activity, and, by the analysis, to precisely determine the parts of the brain which are functionally active. The measurements are taken with millisecond time resolution. The locations of the

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[2] Clinical applications of magnetoencephalography in epilepsy, Ann Indian Acad Neurol. 2010 Jan-Mar; 13(1): 14–22

[3] Preoperative magnetoencephalographic sensory cortex mapping. Stereotact Funct Neurosurg, 2013, 91-314-22

[4] https://megin.fi/what-is-meg/

[5] Magnetoencephalography Slow-Wave Detection in Patients with Mild Traumatic Brain Injury and Ongoing Symptoms Correlated with Long-Term Neuropsychological Outcome, J Neurotrauma. 2015 Oct 1; 32(19):1510–1521

[6] MEG Working Memory N-Back Task Reveals Functional Deficits in Combat-Related Mild Traumatic Brain Injury, Cerebral Cortex, Volume 29, Issue 5, May 2019, Pages 1953–1968

[7] MEG Detection of Delayed Auditory Evoked Responses in Autism Spectrum Disorders: Towards an Imaging Biomarker for Autism, Autism Res. May 2011

[8] MEG biomarker of Alzheimer's disease: Absence of a prefrontal generator during auditory sensory gating, Hum Brain Mapp. October 2017, 38(10):5180-5194

[9] Megin Oy do not manufacture MCG and so these are not included in this exemption renewal request, but are included as they also use SQUID detectors.

[10] SQUID magnetocardiography: status and perspectives, IEEE, Volume 11, Issue 1, March 2001

[11] Routine clinical heart examinations using SQUID magnetocardiography at University of Tsukuba Hospital, IOP, Superconductor Science and Technology, Volume 30, Number 11, October 2017

[12] Diagnostic outcomes of magnetocardiography in patients with coronary artery disease, Int J Clin Exp Med. 2015; 8(2): 2441–2446

functionally active parts of the brain as a function of time can be accurately superimposed onto an MRI or CT[13] images to provide information about the anatomy and function of the brain. MEG allows insights into sensory processing, motor planning and action, cognition, language perception and production, social interaction, and various brain disorders which otherwise would not be possible. It is possible to localize active brain areas inside the brain with a few mm accuracy.

Figure 1. TRIUX™ neo MEG scanner

[13] MRI=Magnetic Resonance Imaging, CT=Computerised Tomography

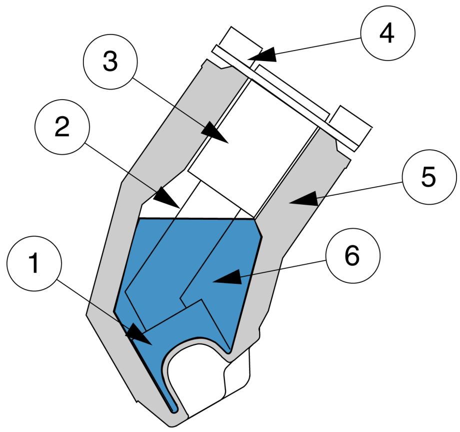

Figure 2. Construction of the probe-1: Wiring unit with sensor elements, 2: Wiring, 3: Neck plug, 4: Preamplifiers, 5: Dewar with vacuum insulation, 6: Liquid helium.

SQUID detectors use Josephson junctions to detect a change of magnetic field as much as 100 billion times weaker than the magnetic field of the earth that moves a compass needle. The Josephson junction consists of two superconductors separated by a thin insulating layer which allows superconducting electron pairs to pass through.

The SQUID detectors employed in MEG are made on silicon wafers using semiconductor fabrication techniques. Each detector comprises a superconducting sensing coil and a SQUID connected together using [redacted]

3 [redacted]

The sensor array comprising 102 three-channel sensor modules is cooled to 4.2K by immersion in liquid helium (in a vacuum-insulated vessel) such that the sensing coils, [redacted] and SQUIDs are superconducting.

[redacted]

Figure 3. [redacted].

A MEG system uses the 102 sensor modules to create an array which is used to map brain activity in three dimensions. There are [redacted] tin-lead alloy bonds per SQUID detector, resulting [redacted] bonds in a singular MEG system, all of which have to be reliable and so play a critical role in the technology. Figure 4 outlines the sensor array configuration, with each of the squares consisting of a sensor module.

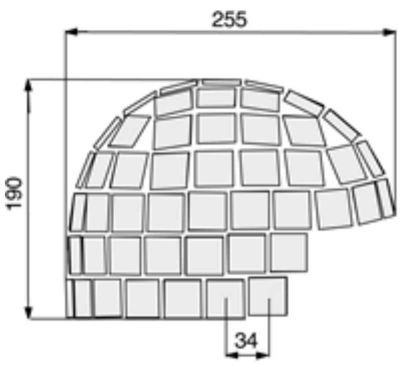

Figure 4 Sensor array side view, dimensions in millimetres

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

Tin-lead to tin-indium are used for connections in SQUID detectors as these alloys have the following technical properties:

- Superconducting below its T_c of 7.3K. Few other metals are superconducting at or above this temperature that are also suitable for soldering, other than lead and its alloys. The whole detector loop is required to be superconducting with zero electrical resistance, or at worst down to the nano-Ohm level resistance as any higher values negatively affects the measurements of the SQUID detector;
- Ideally the critical superconducting temperature (Tc) of the bonding material should be as high as possible as this would allow designs with less liquid helium to be used;
- Resistance to oxidation both in service and during manufacturing is critical to ensure low/zero electrical resistance and the formation of clean metal-to-metal contacts;
- The bonds must have a high degree of proven reliability as it is not possible to build in redundancy into the system to compensate for bond failure. Therefore, there is the requirement for 100% bond reliability. If any bonds were to fail, they would not be able to be repaired at operating temperature, but the whole detector array would need to be warmed up to room temperature for repair. Bond failure would negatively impact image quality in a section of the brain, as well as increase the likelihood of other bonds failing due to the large temperature changes that occur during warming and cool-down required by the repair, potentially causing further bond failures. If bonds cannot be made reliably and more fail during the repair process, it will be impossible to build a properly functional MEG;
- Lead is the most effective additive that inhibits tin pest phase transformation occurring with tin and its alloys at low temperature;
- If repair is required, this will cause the MEG to be unavailable for medical diagnostics for patients and research activities, and patients cannot be measured for 1 – 2 weeks who will suffer as a result;
- Durability of the bonds are crucial as the SQUID detector is cycled from room temperature to 4.2K during the annual servicing of the MEG system. The bonds have to be ductile and flexible as well as being reasonably strong to ensure they are not damaged in service or when boiling liquid helium is introduced which creates an extremely turbulent environment around the SQUID detector circuits; and
- Manufacturability:
    - The process of application of the connectors to the sensors needs to be able to be applied at less than 200°C to avoid damaging other electrical components of the circuit;

- The ability to be soldered without the use of flux which would impact the conductivity and therefore the signal measured by the detector; and
- The bond between the connector and the surfaces of the circuits needs to have sufficient material compatibility to ensure that a good bond is formed. Parameters such as differential thermal expansion between various construction materials (e.g. silicon, lead, niobium wire, printed circuit board made of fibre glass) need to be considered to minimise mechanical stresses which could lead to failures.

The normal lifetime of SQUID detectors is between 10 to 15 years, with known examples of products being used for over 20 years.

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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.)

To date, only a few MEG have reached end of life and of these, Megin are in receipt of most of the systems ever produced as part of their upgrade process. Megin do not know the location of others, but they may still be in use.

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: All parts

☐ 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 articles which are recycled [redacted] grams lead if one MEG reaches end of life during a year. Currently, <1 reaches end of life in the EU annually.

☐ In articles which are sent for energy return _____
☐ In articles which are landfilled _____

6. Analysis of possible alternative substances

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

MEG is a very expensive diagnostic tool which limits its availability and so manufacturers are carrying out research into alternative designs that avoid the need for liquid helium cooling. These alternatives may also avoid the need for superconducting bonds made of tin-lead. Megin has also considered alternatives to lead in SQUID detectors. Both of these options are described below.

Any alternative substance or technology in addition to meeting the required functionality and requirements as outlined in Section 4, needs to maintain or increase the operational temperature in order not to increase the need of liquid helium. Helium is a very scarce element on the Earth with the demand for the element expected to rise dramatically over the coming years. Anything which reduces the requirement for helium will ensure that capabilities such as SQUID detectors, and other applications not covered in this application (such as MRI) are able to be supported, and the environmental impact arising from the extraction, processing and use of this very scarce element is reduced.

Potential alternative superconductors to lead:

As discussed in the ERA, 2006 report[14] and as included in Table 1, there are only a few metallic elements that are superconductors at above 4.2K and many of these are hard, brittle and readily oxidise, so are unsuitable. Currently, only lead and its alloys meet all the technical requirements. The table below lists metallic elements that are low temperature superconductors with comments on their suitability.

[14] ERA, Review of Directive 2002/95/EC (RoHS) Categories 8 and 9-Final Report, 2006

Table 1 Properties of potential alternative metals which might be used for SQUID sensor bonding

Metal	Critical temperature, T_c (K)	Properties
Niobium	9.46	Hard inflexible metal, readily oxidises (this oxide is very inert and can be removed only with hydrofluoric acid), unsuitable as a solder
Lead	7.2	Ductile and flexible. Resistant to oxidation and corrosion
Lanthanum	6.0	Hard inflexible metal, readily oxidises. Unsuitable as a solder
Vanadium	5.38	Hard inflexible metal, readily oxidises, Unsuitable as a solder
Tantalum	4.47	Hard inflexible metal, readily oxidises. Unsuitable as a solder
Tin	3.72	Ductile and flexible, but T_c is too low. Suitable as an alloy with lead as these alloys have a suitable T_c and are ductile and easy to solder and achieve 100% good and reliable bonds. Some other tin alloys also have T_c >4.2K but have disadvantages including the risk of tin pest phase transformation, which occurs at low temperatures.
Indium	3.41	Ductile and flexible, but T_c is too low. Susceptible to oxidation and corrosion. Suitable when alloyed with lead, but alloys with high indium content form inert oxide coatings that make soldering difficult.
Aluminium	1.2	Ductile and flexible, resistance to oxidation and used for wire bonding ICs but T_c is much too low
Cadmium	0.56	Ductile and flexible. Resistance to oxidation but T_c is much too low. Previously used as a constituent of Woods alloy, but this is no longer used as a superconductor. RoHS restricted substance
Gold	Not a superconductor at any temperature	Most elements in the periodic table are not superconductors and gold is just one example.

T_c = Critical temperature, this is the temperature below which the metal conducts electricity with zero resistance.

Reviewing the periodic table for metals that could potentially be used for bonding and are superconductors at >5K, there are no other naturally occurring elements other than those listed in the table above. Technetium has a critical superconducting temperature (T_c) of 7.7K but is a radioactive man-made element[15], so cannot be used (it would also be too hard). Alloys can have higher or lower T_c than the elements. For example, PbBi alloys have higher T_c than pure lead and PbIn has a lower T_c. Alloys of some of the other metals listed in Table 1 have been considered, but most have too low T_c or are also hard brittle metals not suitable for soldering, such as the alloys of lanthanum, vanadium and tantalum. The only potential options are described below.

Bismuth-tin-indium alloys

The recent information on bismuth-tin-indium alloys which are being investigated for MRI applications are currently being considered by Megin as a potential for future systems. Solders based on indium are susceptible to oxidation and corrosion and so are difficult to solder unless a corrosive flux is used. The use of corrosive fluxes is not acceptable as these can cause corrosion which causes failures to the very small bonds. Lead-free tin alloys are also potentially susceptible to “tin pest” (described below).

The addition of bismuth makes the alloy brittle and hard which is a significant disadvantage during the rapid cool down in liquid helium. Cool down and heat up will cause stresses due to thermal expansion mismatch as well as stresses from the churning, boiling liquid helium that could cause fracture of brittle bonds[16].

Megin is also aware of confidential information yet to be published that indicates that bonds trialled with BiInSn and SnBi have demonstrated a small (but too large) amount of electrical resistance in liquid helium which will need further investigation as it would make the alloy unsuitable for MEG applications.

Tin Pest

Tin pest has been known for many decades with most research has been carried out at temperatures between -50 and -30°C because the phase transformation occurs most rapidly within this temperature range and because testing at liquid helium temperatures is very difficult to carry out. The rate of tin pest transformation is highly complex and dependant on a variety of complex factors but can be described as depending on two distinct processes occurring:

- The first is nucleation where minute α-phase particles are formed within the β-phase. The driving force for nucleation is the difference in temperature between 13°C and the actual temperature and so the

[15] Springer Handbook of Condensed Matter and Materials Data pp 695-754 chapter 4.2 Superconductors, downloaded from https://link.springer.com/referenceworkentry/10.1007%2F3-540-30437-1_10

[16] Confidential information provided by another manufacturer is that they found that soldered bonds using BiInSn to niobium alloy in liquid helium had a small electrical resistance so are not superconducting.

driving force for nucleation increases as the temperature drops. Nucleation usually requires a defect such a grain boundary or a particle of impurity but the time for nucleation to occur varies considerably.

- The second process is phase transformation where the α-phase grows from the initial nucleation sites. The rate at which this occurs also varies considerably depending on the alloy composition and its history (as this affects crystal structure) as well as the temperature.

Unlike other physical processes, it is not possible to artificially accelerate tin pest. Many physical processes are accelerated by raising the temperature but this is not possible for tin pest because if temperature is increased, nucleation is retarded and no transformation will occur if the temperature exceeds 13°C. Research therefore needs to be carried out for periods that are similar to the lifetime of the Megin product used and temperature histories used, this can be up to ten or more years. Therefore the reliable lifetime is uncertain for all other tin alloys, especially if they have been shown to suffer from tin pest more rapidly than tin/lead. Tin/lead alloys have been used for several decades at liquid helium temperatures (in MEG and in MRI) without tin pest failures. Testing of lead-free solders has been published and one researcher[17] found that they suffer from tin pest significantly sooner than tin/lead although this work is with bulk samples and there is evidence that very small solder bonds may behave differently. Testing of very small solder bonds made with lead-free solders (for >10 years) has not been published and has probably not been carried out as most University research projects are limited to about 3 years.

Potential alternatives to lead:

Niobium wire bonds

Ultrasonic niobium wire bonding was researched by Megin's subsidiary as part of their in-house testing of alternatives. The niobium bonding was tested on the MEG system without helium submersion of the sensors to investigate the reliability of the bonds using this alternative material and bonding method. Niobium wire was used because it is a superconductor and is used for the SQUID magnetic field detector loops

The testing revealed that the reliability of the bond for the niobium wire between the niobium loop and the chip pads was inadequate with only 70-80% achieving the required properties (good very low resistance bonds) and so >20% were unsatisfactory. In comparison with the lead/tin to lead-indium alloy where 100%

[17] W. J. Plumbridge, "Further Observations on tin pest formation in solder alloys", J. Electronic Materials, Vol 39 (4), p 433, 2010.

of bonds can be manufactured to the required standard, so the ultrasonic niobium bonding method could not be considered as an alternative to lead alloy bonding.

Compounding the bond formation issue and adding to the consideration to deem niobium wire bonds to be not a viable alternative was the following observation made in another project carried out by Megin: Some sensors employing niobium wire bonds were found to have a small electrical resistance in the sensor coil -SQUID connection. This was demonstrated by the observation of a low-frequency drift in the output signal from the superconducting loop after a change of ambient magnetic field due to, e.g. shielded room door closure, rather than a stable measurement which is required to be achieved. MEG must be used in a shielded room because the brain signals being measured are much smaller than the earth's magnetic field and the electromagnetic interference originating from other electrical equipment. Opening and closing the room door should not affect the SQUID detector's output.

Replacement of superconductor technology as a potential alternative to lead use:

Optically-pumped magnetometers (OPMs):

Megin are part of the macQsimal project; an EU-funded Horizon 2020 research project which aims to design, develop, miniaturise and integrate advanced quantum-enabled sensors with outstanding sensitivity, to measure physical observables in five key areas: magnetic fields, time, rotation, electro-magnetic radiation and gas concentration. For clarification: Megin originally joined the macQsimal project under the legal entity name as Elekta Oy. However the legal entity name was recently changed to Megin Oy.

Megin is an industrial partner in the project, providing an industry viewpoint in the Optically-Pumped Magnetometer (OPM) work-packages. MacQsimal is a three-year project, which has two years remaining at the time of submission of this exemption request. The objective of the project is to design, develop, and validate OPMs for measuring low frequency magnetic fields in biomagnetic, scientific, and medical applications. The project will be a sensor technology demonstration, equating to a technology readiness level (TRL) of 4-5 and, therefore, will require considerable further development once it is completed.

OPMs are being developed as a potential alternative to cryogenic, superconducting MEG systems. They have the benefit of not requiring cooling, and, therefore, potentially allowing sensors to be placed closer to the head[18],

[18] Although there are indications that OPM sensors may be too warm to move closer to the patient

increasing the sensitivity in comparison with SQUID detectors[19].There would also be the significant advantage of lower costs, which would allow this technique to be more widely adopted by EU hospitals than at present. Optical pumping refers to the use of a light source such as a laser or discharge lamp to cause absorption or emission of energy by a sample at a precisely defined frequency, changing the sample's quantum state. Although this technology showed, in late 1950s and early 1960s, that optical pumping can be used for inducing a magnetically sensitive state in an atomic system and, therefore, allow for the measurement of weak magnetic fields, the technology still faces significant technical challenges before it can be deployed. The following are outstanding technical considerations which would need resolution:

- One of the most significant issues, which may not be able to be resolved with this technology, is the reduction in bandwidth of OPM in comparison with SQUID detectors. The present OPM sensors have sufficient sensitivity up to around 100 Hz[20], while SQUID-based detectors are capable of measuring signals at several kHz, with an example from Megin offering 1.6 kHz as standard.
    - A large bandwidth is particularly important for some applications such as brain stem measurements. The bandwidth of the brain signals spans typically from 0.1Hz up to 600-800Hz, some of which would be unable to be measured by OPM;
    - Clinically relevant high frequency oscillation at about 200Hz relating to epilepsy would also be unable to be conducted with the OPM bandwidth currently available; and
    - Brain research undertaken with SQUID detectors often require the broadest range of bandwidth, which would be unable to be supported with the OPM bandwidth currently offered. Currently around 50% of Megin’s SQUID detector MEGs are sold for research applications, and, therefore, the limited bandwidth of the OPM sensors would negatively affect multiple research applications.
- Related to limited bandwidth, the sensitivity over the bandwidth for OPM is not constant, which requires compensation. Although this issue in time could be resolved, this will require the use of negative feedback technology which has not been used so far with OPM-based sensors;
- The OPM sensors that are sensitive enough for MEG applications have the requirement for zero field operation as they are absolute field sensors, requiring extremely good shielding from the earth’s magnetic

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[19] Optically pumped magnetometers: From quantum origins to multi-channel magnetoencephalography, 2019 from https://discovery.ucl.ac.uk/id/eprint/10075433/

[20] Example OPM currently offered which outlines typical technical specifications- https://quspin.com/products-qzfm/

field and disturbance from electrical sources. To be able to achieve the required level of shielding, active field compensation is required, which is still in development. In comparison, SQUID-based sensors require a constant but not a zero field which is achieved inside a shielded room;

- The signal is currently affected by higher noise generation, which could be compensated by a closer proximity to the patient. However, the high power demands currently required by the technology generate large amounts of heat in the system, which impacts the allowable proximity to the patient; and
- There are also current limitations on the proximity of sensors to each other due to cross talk issues, meaning that the sensors interact if placed too close to each other. This interaction affects the signal and, therefore, reduces the useful signal produced by the detector.

The technological challenges facing OPMs are currently being worked upon in the macQsimal project, which will take a number of years to complete. Once this project has ended, there will be considerable further work to develop a system level solution (TRL 8-9) and establishing sufficient system level data on reliability to gain global regulatory approvals before launching the new technology. It currently seems unlikely that OPM-based MEG systems can replace all SQUID-based MEG systems due to their smaller bandwidth. Therefore, SQUID-based MEG systems will probably also be needed for the medical and research applications that require >100Hz detection.

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

Please see Section 6 (A), which includes test data using niobium wire bonding that gives at best only 80% yield compared to 100% with lead soldering. More than 20 years of field data and more than 120 MEG-systems produced by Megin with lead solder show that these are very reliable. It is not possible to produce a commercially viable MEG with [redacted] bonds where >20% fail because reworking is likely to create more faults and 100% good bonds will never be achieved.

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.

Refer to Section 6 for recent research into substitution of lead

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

The magnetic field sensors are the core technology of the MEG due to the high sensitivity requirement. Changes that might have an impact on the reliability require extensive testing. Changes in the key technologies, specifications and operating principles (e.g., change from SQUIDs to OPMs) require clinical trials before regulatory approvals can be submitted. Typical timescales are as follows:

Table 2 Predicted timescales for the development of OPM based solution

Phase	Elapsed time
MacQsimal project, resulting in TRL4-5 sensor	2 more years (from 2019)
Development of the sensor to TRL level 8-9	[redacted]
System development, resolving screening issues, design of sensor array, ancillary controls development, etc.	[redacted]
Clinical trials and regulatory approval	[redacted]
Total Cumulative Time	[redacted]

The timescales as outlined in Table 2 are based on the premise of successful testing is achieved and that phases do not have to be duplicated due to alternatives not being able to achieve the required performance. Due to the technological challenges undertaken in the development of an OPM based solution the engagement of research and technology organisations, academic and industrial partners is critical and without their specialised knowledge the timescales in Table 2 would only be lengthened.

It should be noted that OPM based solution may only be able to replace dedicated applications of SQUID-based MEG due to potential limitations with the technology, as described in Section 6 (A), rather than the full spectrum of solutions currently offered by SQUID-based MEG.

Even though the likelihood of success as explained in Section 6 (A) seems low, the alternative bismuth-tin-indium solder (and other potential alloys) option will be investigated further by Megin. The timescale is impossible to predict due to the missing proof-of-concept and the high uncertainty related with these materials.

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

2) Provide REACH-relevant information received through the supply chain.
Name of document: Lead metal registration – see https://ila-reach.org/our-substances/lead-metal/ and https://echa.europa.eu/registration-dossier/-/registered-dossier/16063

(B) Elimination/substitution:

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

☐ Yes. Consequences? _____

☒ No. Justification: There are no current alternatives that provide a technical solution

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

☐ Yes.

☐ Design changes:
☐ Other materials:
☐ Other substance:

☒ No.

Justification: The only possible alternative is a different material for bonding or an alternative technology which does not require cryocooling. Currently both of these options require a significant amount of development and testing to determine if it will be possible to provide the same level of performance and reliability currently required by the applications that use SQUID detectors.

3. Give details on the reliability of substitutes (technical data + information): Not applicable (except see Section 6(B)), as there is no technical alternative currently available with sufficient reliability and performance.
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: _____
   2) Health impacts: _____
   3) Consumer safety impacts: _____

⇨ Do impacts of substitution outweigh benefits thereof? Not applicable
Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

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 OPM would be cheaper than SQUID
d) What conditions need to be fulfilled to ensure the availability? See Section 7 (B)

(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- Without this exemption, reliable SQUID-based MEG systems could not be sold in the EU, which would be a significant disadvantage to EU hospitals and research institutions as a key diagnostic ability would be lost and research efforts would also be impeded.

The annual cost to society of brain disorders in Europe has been estimated at 800 billion Euros[21]. Much of the cost is due to inadequate diagnostics and lack of early intervention, e.g. in epilepsy or neurodegenerative pathologies, leading to institutionalisation and/or inability to work. In Europe there are 6 million children suffering from brain disorders, and the cost of their care is 21 billion Euros[22]. Due to the ionising radiation used for the most common brain function imaging tool, PET, this is of limited use with children (PET requires that patients consume radioactive isotopes that are used for imaging).

Many if not most brain disorders involve dynamic aspects[23] and connectivity dysfunction; these cannot be studied with conventional means such as CT, MRI, or PET. MEG, with its exceptional spatial and temporal accuracy, offers a solution to this problem but is reliant on the use of lead in superconducting connections.

If manufacturers were forced to replace lead without a fully developed alternative including time for reliability testing, three scenarios could result:

a. They would not gain Notified Body approval so MEG could not be sold in the EU;
b. If an alternative technology were used, but reliability is found in the future to be inferior, unexpected failures would cause inferior data quality and delays in medical diagnosis with resultant negative health impacts and unexpected delays in research programs. Repairs to detectors takes 1 – 2 weeks in which time, the MEG cannot be used; or
c. If lifetimes were very much shortened by detector failures, this would very significantly increase costs incurred by EU hospitals and research institutions due to the need for more regular maintenance and replacement. The estimated cost to fix 2-3 channels due to the failure of a connection would be thousands of euros each time.

As about 50% of MEG are used for medical research, this would also not be possible in the EU so that EU Universities, Institutions and Companies could not

[21] The economic cost of brain disorders in Europe. European Journal of Neurology, 2012, 19:155-162

[22] Cost of disorders of the brain in Europe 2010. European Neuropsychopharmacology, 2012, 21:718-779

[23] Dynamical diseases. Nature, 1978, 272:673–674

compete with laboratories in non-EU countries. This would result in loss of EU jobs and a decrease of EU competitiveness in basic and clinical brain research.

☐ Possible social impacts external to 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:

The technological demands of finding an alternative to lead as a connective material in SQUID detectors is high. Megin is committed to only using RoHS exemption requests when necessary and has ensured that the number utilised is minimised. Megin has modified all of their electronics to be RoHS compliant and has developed alternative pin connections such that it no longer relies on Exemption 25 of Annex IV. Megin has also monitored the supply chain removal of lead in cryocoolers (exemption 29 of Annex IV). These applications have removed much larger quantities of lead from the MEG system than is used in SQUID detectors. Megin is carrying out extensive research to replace lead but this involves many very significant technology challenges that need to be resolved.

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10. Information that should be regarded as proprietary

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

Exact practical details of making of the superconductive bond, dimensions, compositions and form etc. Details and schedules of OPM projects other than publicly known (EU funded project). These are trade secrets.
