Exemption Request Form

Date of submission: 12 September 2018

1. Name and contact details

1) Name and contact details of applicant:

Company:	GE Healthcare	Tel.:	+1 262 548 2051
Name:	James P. Vetro	E-Mail:	James.Vetro@med.ge.com
Function:	Principal Engineer & GE Healthcare Business Leader	Address:	3000 North Grandview Boulevard, Waukesha, WI 53188 USA

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: Annex IV
- ☐ Request for amendment of existing exemption in
- ☐ Request for extension of existing exemption in
- ☐ Request for deletion of existing exemption in:
- ☐ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☐ Annex IV

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: Bis-(ethylhexyl) phthalate (DEHP) in plastic strain relief devices used to prevent damage to cable connections to MRI imaging coils

Duration where applicable: Until January 2024

☐ Other: _____

3. Summary of the exemption request / revocation request

GE Healthcare requests an exemption to extend the time period to replace the existing materials of MRI coil cable strain reliefs and for designing strain reliefs with an alternative material and design modifications required to attain adequate performance with the new design. Tests using alternative materials show that this would either fail in service much sooner than currently used materials and so would be unreliable or could adversely affect image quality. There would also be negative health and socio-economic impacts without this exemption that are explained in section 6 of this 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) send and receive coils

   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

   ☒ DEHP

3. Function of the substance: DEHP is added to polymers to provide flexibility

4. Content of substance in homogeneous material (%weight): 10 – 50%

5. Amount of substance entering the EU market annually through application for which the exemption is requested: 40 kg DEHP annually.

Please supply information and calculations to support stated figure

The calculation method includes confidential information and so has been submitted separately.

6. Name of material/component: Bis-(ethylhexyl) phthalate (DEHP) is an additive in flexible PVC polymers, which is used as strain relief boots. An example is shown below in Figure 1.

Figure 1. MRI coil for imaging shoulders. These connect to the MRI via the four strain relief boots shown above (circled in red).

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?

MRI are large very complex medical devices that are used to obtain three-dimensional images of parts of the human body including soft tissue, internal organs, muscles and blood vessels. MRI images are obtained by exposing patients to very high strength magnetic fields and radio frequency (RF) signals. The RF electric field interacts with protons in molecules of the patient's body which emit weak RF signals that are detected by specially designed receive coils. The received signal is used to generate the image. Many hundreds of different types of receive coils are made for imaging specific parts of the body and each type of MRI uses its own types of receive coil. Receive coils are made, for example, for shoulders (as shown above), heads, hands, heads, feet, etc. The receive coils are connected via cables to the MRI and the coil itself is placed on the skin of the patient.

It is important that the materials used for coils, including cables and strain reliefs do not adversely affect image quality. MRI functions by detecting protons (hydrogen atoms in molecules of the human body) and so will be sensitive to protons in coils and strain reliefs that are close to the patient. Coils, strain reliefs and cables are designed to minimise any effect on image quality, but choice of polymers and additives in polymers can affect image quality if these have strong proton signals.

Medical devices that are used in physical contact with patients' skin must meet a range of criteria as explained below in 4 (C).

MRI and the associated coils are long-lifetime products that must be very reliable because if a part were to fail so that it is not possible to use the MRI or a coil, the patient who may be very ill, could not be treated. Where flexible cables are attached to rigid electrical components such as shown above in Figure 1, they will flex repeatedly in use. Repeated flexing will cause both the electrical insulation and the internal copper wires to fracture as a result of mechanical fatigue. This will cause the coil to fail and not be usable. This failure mode is commonly prevented in many types of electrical equipment including MRI coils using flexible plastic components that limit flexing movement. These are often referred to as strain relief boots. There are many designs on the market, but the important property is that the wire can flex for sufficient times without fracture during the expected lifetime of the equipment. By reducing the

angle of movement of the wire where it connects to the rigid connector (see below), this greatly extends the lifetime of the cable and its connection.

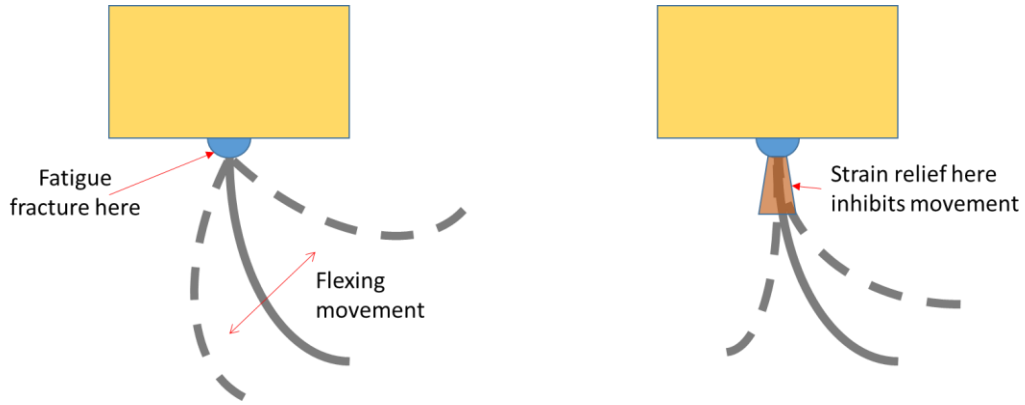

Figure 2. Effect of cable strain relief on movement of cable at connection to equipment

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

All of the following are required:

- The polymer plus all additives including the plasticiser must be acceptable for use in medical devices. New materials must comply with biocompatibility requirements according to ISO 10993 “Biological evaluation of medical devices”, before they can be used.
- Lifetime of at least 8 years of frequent use and without failures. This is on average equivalent to 30,000 repetitive bend cycles
- Must not affect MRI image quality, so must be non-magnetic and have a proton signal emission material / air ratio as low as possible, ideally <1.2, but must be <4.0 when within the imaging zone (i.e. strain reliefs that are attached to coils)
- Coil assemblies must not be damaged when a patient has to be rapidly removed from a MRI scanner in an emergency, for example, if they suffer a heart attack. This is important if coil assemblies have to be redesigned.

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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.)

No, these are disposed of by recycling at end of life

2) Please indicate where relevant:

☐ Article is collected and sent without dismantling for recycling

☐ Article is collected and completely refurbished for reuse

☐ Article is collected and dismantled:

☐ The following parts are refurbished for use as spare parts: _____

☐ The following parts are subsequently recycled: _____

☒ Article cannot be recycled and is therefore:

☒ Sent for energy return – PVC strain reliefs are incinerated when the coils are processed to recover copper, lead, gold and other recyclable metals from the wires. Lead may occur in RoHS exempt forms and must be safely recovered by recycling.

☒ 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 _____

☒ In articles which are sent for energy return 20kg

☒ In articles which are landfilled 20kg

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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

There are many strain relief boots advertised for sale in the EU but many are made of PVC that contains DEHP. Medical device manufacturers cannot however use strain relief boots that are designed for electrical equipment and made with alternative polymeric materials to DEHP-PVC because these alternative polymers are not approved for human skin contact medical

use. Only substitute materials that pass the tests of ISO 10993 are acceptable as well as meeting all of the other requirements that are listed in section 4 (C).

Three options are being considered:

a) Substitute polymers or

b) PVC with alternative plasticisers

c) Avoid using strain relief boots by redesign

Evaluation of alternative polymers

Due to the increasing number of substance restrictions and potential restrictions that affect PVC[1], some medical device manufacturers are reluctant to use an alternative based on PVC as they will not want to be forced to substitute again in the future. Several other types of polymer have good biocompatibility but their flexibility will not be identical to DEHP-plasticised PVC and most are less flexible and so they may have shorter lifetimes in MRI coil assembly. If the strain relief is less flexible the cable's movement at the end of the strain relief will be larger which increases the risk from fatigue failure. Similarly, if the strain relief material is too flexible it will be less effective at reducing the movement angle of the cable at the contact location and this could fracture prematurely.

Nylon is less flexible than DEHP-plasticised PVC but has good biocompatibility and so this has been evaluated by General Electric Healthcare and the test results are as follows:

Accelerated test results for potential alternative material

Strain reliefs using a Nylon polymer were made through a moulding process and then tested on a cable to determine if the cycle life of the strain relief would be adequate in the application. These strain reliefs were flexed in a manner similar to that shown in Figure 2 which represents the movement that will be seen in daily use.

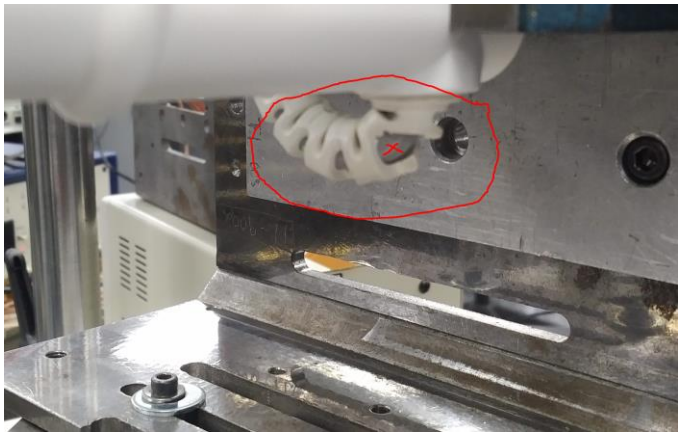
The strain reliefs were flexed and began cracking at 4000 cycles. Testing was continued to 15,000 cycles and the strain reliefs developed cracks through their body as shown below. Once cracked, the strain relief will no longer perform its intended function to decrease the stress on the cable protecting the insulated wire inside the cable. In the estimated useful 8 year life-span of a coil, conservative estimates indicate a need for at least 23,000 cycles. This is based on 200 working days per year for 8 years and an estimated 14 scans per day. Some health care providers if specialized or running multiple working shifts will incur a greater number of cycles sooner. This is an estimate. At the time cracking began at 4000 cycles with the new nylon strain relief, the strain relief is considered failed. No observable cracks during the normal lifespan is required for ability to adequately clean the device between patient uses and to maintain an acceptable appearance. Operator manuals for the Coils indicate that any item

[1] For example the proposed RoHS restriction of diantimony trioxide

showing physical damage such as a crack should be removed from use and sent to service immediately.

Two photos acquired during the testing are below asFigure 3. An X is marked on the area of fracture and then final separation in the second picture.

Figure 3. **Cracked Bending Cycle**



Separated After Test

Results with nylon suggest that alternative polymers that are less flexible than plasticised PVC are likely to be unsuitable. Most flexible polymers are less flexible than plasticised PVC. Therefore, alternative plasticisers for PVC are also being evaluated.

Evaluation of substitute plasticisers in PVC

PVC is widely used for cables in MRI because it exhibits a relatively small proton signal and so does not impair MRI image quality. Also, it has been used for over 20 years and so manufacturers have enough field data to know that it is reliable and has no harmful effects on patients. GE is evaluating possible substitute plasticisers in PVC strain reliefs and to minimise changes in performance, has evaluated the similar, but less hazardous diethylhexyl terephthalate. This has a chemical structure that is very similar to DEHP so it was hoped that it would not have a large negative effect on the MRI proton signal as well as giving a similar

flexibility. The same flexibility can be achieved if sufficient plasticiser is added to the PVC, but its viscosity is higher than that of DEHP:

DEHP Viscosity 56.6 mPa.s at 25°C

Diethylhexyl terephthalate[2] Viscosity 65 mPa.s at 25°C

As diethylhexyl terephthalate is more viscous than DEHP, more needs to be added to the PVC to achieve the same flexibility.

The first comparative testing to be carried out is MRI proton signal intensity measurement. Comparative tests with two grades of PVC were used, one being more flexible than the other. The more flexible versions are used for the strain reliefs furthest away from the patient and the less flexible material is used to attach the cable to the coil itself. Strain reliefs made with DEHP-PVC and diethylhexyl terephthalate-PVC (DEHT-PVC) were compared and the relative image intensity ratio from the polymer versus air was measured. Measurements were made within a range of "flip angles" because not only is image intensity important, but contrast between materials is also important (intensity and image contrast both vary with flip angle). Results are shown below:

Table 1. Results for more flexible materials, durometer value 65

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	10	17	17	17.1	15.7	15.1	13	12.4	9.9	6.2
DEHT ratio	10.8	19.4	19	21	19.9	18.4	15.4	15.2	11.4	7.4
Increase in ratio	0.8	2.4	2	3.9	4.2	3.3	2.4	2.8	1.5	1.2
% higher	8.0	14.1	11.8	22.8	26.8	21.9	18.5	22.6	15.2	19.4

Table 2. Results for less flexible materials, durometer value 90

Flip angle	1	2	3	4	5	6	7	8	10	15
DEHP ratio	1.6	2	1.7	1.9	1.8	1.8	1.5	1.4	1.1	1
DEHT ratio	1.8	2.4	2.5	2.5	2.3	2.1	1.8	1.8	1.5	1.1
Increase in ratio	0.2	0.4	0.8	0.6	0.5	0.3	0.3	0.4	0.4	0.1
% higher	12.5	20.0	47.1	31.6	27.8	16.7	20.0	28.6	36.4	10.0

The above results show that the DEHP-PVC material with durometer of 65 has too strong a signal for use close to the imaging zone as the relative image intensity values are more than 4.0. This material is therefore only used at least 30 cm away from the imaging zone where it has no detrimental effect. The results of the 65 durometer material with diethylhexyl terephthalate-PVC show that this has an even higher image intensity than DEHP-PVC, which indicates that it could give inferior imaging performance to DEHP-PVC. Results with the less

[2] http://www.lemonchem.com/wap_product_detail_en/id/10.html

flexible 90 durometer material also show that diethylhexyl terephthalate-PVC gives a higher proton signal intensity than DEHP-PVC. Although all values from the 90 durometer material are within the 4.0 ratio limit, they are mostly higher than the ideal 1.2 limit with both materials (except at flip angles of 15°), but values are much closer to the 1.2 ideal ratio with DEHP-PVC than with diethylhexyl terephthalate-PVC. Diethylhexyl terephthalate-PVC is again therefore inferior to DEHP-PVC so could affect image quality under the most demanding imaging conditions.

The most likely explanation for these results is that protons (hydrogen atoms) in the plasticiser molecules give much stronger MRI signal intensity than protons in the PVC polymer. This is indicated because 65 durometer PVC contains more plasticiser than the less flexible 90 durometer material and gives a stronger proton signal. The intensity of protons in the diethylhexyl alkyl groups of the terephthalate and the phthalate may be similar, but due to the higher viscosity of diethylhexyl terephthalate, a higher concentration must be used to achieve the same flexibility as DEHP-PVC to achieve the 90 durometer value. This result therefore indicates that other plasticisers that are more viscous than DEHP are also likely to have stronger MRI signal intensity (as higher concentrations would be needed) and so would also be less suitable than DEHP. The viscosity values of the two most commonly used substitutes for DEHP are higher than DEHP, as shown below:

Table 3. Viscosity of phthalate plasticisers

Phthalate	Viscosity (source of data)
DEHP	56.6 mPa.s (25°C), from Eastman SDS
DiNP (di-isononyl phthalate)	85 – 100 mPa.S (20°C), from ExxonMobil datasheet
DiDP (di-isodecyl phthalate)	110 – 125 mPa.S (20°C), from ExxonMobil datasheet

At present, it appears that diethylhexyl terephthalate-PVC will be inferior to DEHP-PVC and other more viscous plasticiser will also be inferior. The biocompatibility and repetitive bend performance of diethylhexyl terephthalate-PVC are at present unknown and more time will be needed to carry out these tests. There is no certainty that these will be acceptable and as MRI proton signal intensity was inferior, alternative materials may be preferred.

Impact on healthcare in the EU

Another issue would be the impact on healthcare providers in the EU if many types of MRI coils cannot be purchased by EU hospitals because manufacturers are unable to replace the DEHP-plasticised PVC strain relief boots either because compliant versions which meet all essential criteria cannot be developed or if the value of future sales is considered to be smaller than the potential substitution cost, which can be very significant. The latter is more likely to

occur if the only option is redesign (discussed below) because the costs for testing and trials is more likely to be relatively large and could exceed future profits. The costs include having to test all new coil assembly designs for reliability and performance as each design is different. The extent of movement and the stresses and strains of each strain relief depends on the design of each assembly and the coils vary in size and shape considerably to accommodate different parts of the human body.

Each manufacturer may make up to 100 different design of coils or more. When a hospital buys an MRI, it will also buy the coils that it believes will be frequently needed, but in the future, they may need to buy additional coils to image other parts of patient's bodies. Each MRI model will be made and sold over many years; a period much longer than is typical for consumer products. It is common for one model to be sold for over 10 years and the same types of coils designed for this MRI will be made and sold during this period and for several years after the last MRI of this model is sold. GE MRI generally can only use GE's coils and this situation is the same for all manufacturers' coils. Therefore, without this exemption, many types of coil will no longer be available to EU hospitals.

Without this exemption, manufacturers will have to make many types of coil designs obsolete either because DEHP-free strain reliefs cannot be obtained that meet all of the essential performance and reliability requirements or because the substitution costs would make continued production uneconomic. It would be unreasonable to significantly increase prices of coils to fund substitution research as EU hospitals all have limited funds and would not be able to buy coils that are considerably more expensive.

Currently there are more than 1900 GE MRI scanners installed in European hospitals which may correspond to a slightly lower number of EU hospitals. All of these hospitals and their patients will be affected negatively in their ability to provide MRI scan examination to patients if this exemption is not accepted. If hospitals are unable to buy the current wide range of MRI coils for their MRI scanners that they already own, the waiting time for receiving an examination are bound to increase and many patient's conditions would be more difficult to diagnose and treat as other less suitable methods would have to be used, if this is possible. For example, a whole body coil can be used to examine all parts of a patient's body, but the detail obtained for a small area such as a foot is less than that which can be obtained by a dedicated foot coil. Also, the time required to obtain a scan of a whole patient is much longer than a foot scan and this can cause delays, as MRI demand often exceeds their availability. Other techniques may not be suitable, for example, CT (Computed Tomography) is used to obtain 3-dimensional images of patients, but the information it provides is not the same as from MRI images, not to consider the unnecessary exposure to radiation

From online sources[3], one MRI scanner typically treats around 4,500 patients per year (this is old and conservative data from 2004, the number is higher today). The impact described above

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2645123/

on healthcare for patients can therefore affect more than 9,000,000 patients in Europe per year who could not be treated using the most suitable diagnostic equipment.

Another potential impact on healthcare could be the forced adoption of a less performing material, e.g. inferior image quality or shorter lifetime. Given the limited time left for substitution and the difficulties explain above, GE (and possibly other manufacturers) may be forced to adopt a less performing alternative to avoid not being able to supply coils. A regrettable substitution that will ultimately impact patients by providing less precise diagnostic or inferior reliability that prevents patients from being treated when needed. However, producing coils that are knowingly less reliable is not permitted by the Medical Devices Regulation and could result in withdrawal of EU approvals.

Impact of retarding new product innovations and development

Another impact from substitution is described here. Medical device manufacturers are aware that the availability of trained engineers is limited and employers can choose whether these work on substitution or on new product development. Recruiting more experienced engineers is difficult as most of these will already be working for their competitors, so having to expend more effort on substitution can have a negative impact on innovation which can negatively impact on future health of EU citizens as explained below.

Diverting engineers away from new product development to modifying existing coil designs could negatively affect the 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 or superior medical procedures and treatments. 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[4]. 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 or would at best be delayed if the engineers were diverted to redesign existing products for compliance purposes, but without performance improvement, as would be the case with alternatives to DEHP in strain reliefs. Quantitative life cycle comparison of the following two scenarios is however not possible:

Scenario a) developing new medical devices or

Scenario b) replacing DEHP

This is because the positive and negative impacts of each scenario are not directly comparable with each other and the potential impacts for hypothetical future developments cannot be quantified. However, these two scenarios can be compared qualitatively.

New medical products should usually have a smaller overall health and environmental impact to older designs because medical device manufacturers try to avoid using hazardous

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

substances in new designs as is required by a Medical Device Regulation standard[5]. Compliance with this standard could also give benefits at end of life. Substitution of DEHP should also have a benefit but DEHP is only one of the substances used, none of the other substances used for manufacture will be affected by substitution of one substance (DEHP) in a current product.

The largest potential benefit from new medical device development is at the use life cycle phase where the new technique will improve the health of EU citizens. There is no benefit from replacement of DEHP during the use phase as existing strain reliefs are approved for use in medical devices in the EU.

Although it is not possible to compare quantitatively the development of a hypothetical new medical device with replacement of DEHP in coil strain reliefs, it is clear that new medical device development could potentially give a more significant overall benefit than DEHP replacement.

Alternative coil designs without strain relief

This is a theoretical substitute that is being considered by GE Healthcare, but at present, alternative designs with proven long-term reliability have not been developed by GE Healthcare. This substitution option is much more complex than replacement of an additive in a polymer as the entire coil assembly has to be redesigned. GE makes over 70 different coils, which is a typical number for most coil manufacturers, and every coil assembly would need to be redesigned, fully tested including repetitive bending, proton image intensity measured, biocompatibility, etc. and also tested with patients before re-approval under the Medical Devices Regulation can be obtained from an EU Notified Body as well as approval in other countries outside of the EU. As every coil design is different, redesign would need to be carried out mainly sequentially and so for over 70+ coils, this would take many years and could not be completed by July 2021.

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

Tests carried out using nylon as a possible substitute are given above in section 6 (A).

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7. Proposed actions to develop possible substitutes

[5] 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”

(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.

Research by GE Healthcare to identify substitutes has been described above in section 6. There is no other relevant research by other organisations that has been published.

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

Medical device manufacturers need the following:

- Identify suitable alternative materials
- Measure MRI image intensity
- Carry out biocompatibility testing
- Manufacture strain relief boots for MRI coil assemblies and carry out reliability testing including repetitive bend testing

If results are satisfactory, medical device manufacturers are obliged by Medical device legislation to carry out internal verification and in some circumstances, requesting re-approval may be required. For this type of change, the most likely requirement is re-verification for each MRI coil design that is changed. .The timescale needed for substitution of the strain relief polymer for one MRI coil is:

Phase	**Elapsed time for one coil**
Identify materials	Not known at present
Biocompatibility and other tests	Ca. 6 months
Reliability testing	1 – 2 years
Verification and global approvals if needed	Up to 2 years

The timescale for redesign of over 70 MRI coils would be much longer than for one coil although only a representative selection of coil assemblies would need to be fully evaluated. GE Healthcare predicts that as long as a suitable substitute material can be identified, full substitution of DEHP-PVC with a DEHP-free material could be complete by January 2024.

There is however, uncertainty over the material substitution option as it is not known whether a suitable material can be identified that meets all of the criteria listed in section 4C. The alternative option of coil redesign is also uncertain as this work has only recently started. It would also take considerably longer than

material substitution as more trials and EU Notified Body approval would be needed.

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8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

☐ Authorisation

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

☒ Restriction

☐ Annex XVII - restricted only in children's' and childcare products, so not applicable

☒ Registry of intentions - a restriction on materials with prolonged skin contact has been proposed. Strain relief boots of MRI coils will not have prolonged or frequent skin contact and so would be out of scope. Medical staff are instructed to route cables and the associated strain reliefs away from patients' skin.

☒ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: DEHP registration: https://echa.europa.eu/registration-dossier/-/registered-dossier/15358

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated? See 6 (A) above

☐ Yes. Consequences? _____

☒ No. Justification: See section 6

2. Can the substance named under 4.(A)1 be substituted? See 6 (A) above

☐ Yes.

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

☒ No.

Justification: See section 6

3. Give details on the reliability of substitutes (technical data + information): See 6 (A) above
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
    1) Environmental impacts: See 6 (A) above
    2) Health impacts: See 6 (A) above
    3) Consumer safety impacts: See 6 (A) above

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

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Although many flexible polymers are available, they cannot be used until the work described above has been carried out and they are proven to meet all of the essential criteria

b) Have you encountered problems with the availability? Describe: Suitable substitutes have not yet been identified

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? More time is needed

(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 – for research, testing and re-approvals

☐ Increase in overhead

☒ Possible social impacts within the EU See 6 (A) above Negative impact if hospitals cannot buy additional coils. If hospitals are unable to buy the current full range of coils, diagnosis and treatment times will be longer and some alternative method that have to be used may be less effective.

☐ Possible social impacts external to the EU – none as most countries do not yet restrict DEHP

☐ 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:

The calculation method for the quantity of DEHP placed on the EU market in this application includes confidential market information and a proprietary design