# Exemption Request Form

Date of submission: 06 October 2017

## 1. Name and contact details

**1) Name and contact details of applicant:**


| | | | |
|---|---|---|---|
| Company: | ACIST Medical | Tel: | 952-656-2408 |
| Name: | Jason Malone | E-Mail: | Jason.malone@acistmedical.com |
| Function: | Sr. Electrical Engineer | Address: | 7905 Fuller Road,<br>Eden Prairie, MN 55344 |


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

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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

☐ 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: 42

Proposed or existing wording: Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation.

Duration where applicable: ACIST is applying for renewal of this exemption for an additional validity period of 7 years.

☐ Other: _____

## 3. Summary of the exemption request / revocation request

Directive 2011/65/EU Article 5(1)(a) Annex IV Exemption point 42 will expire 30 June 2019 unless an exemption extension is granted by the Commission before the expiration date. This request is in regards to the extension of the current Directive 2011/65/EU Article 5(1)(a) Annex IV exemption point 42 which is stated as follows: "Mercury in electric rotating connectors used in intravascular ultrasound imaging systems capable of high operating frequency (> 50 MHz) modes of operation."

As pointed out in the previous submission, there are several key requirements this component must meet in order to maintain system functionality. They are as follows:

Voltage:
Amp Rating:
Max. Freq.: >80 MHz
Contact Resistance: <1Ohm
Max. RPM: 3600
Temp Max. F (C)/Min. F (C): 140 (60)/45(7)
Rotation Torque (gm-cm):
Life: 300 Million rotations

As non-mercury alternatives have been introduced and reviewed over the last several years, there have been no alternatives identified that could meet the requirements needed to maintain system performance for use in the ACIST HDi IVUS System. These requirements are essential for the usability, safety, function and reliability of the system. There currently is not a suitable replacement for the mercury wetted slip ring.

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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: ACIST HDi IVUS System

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: None

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

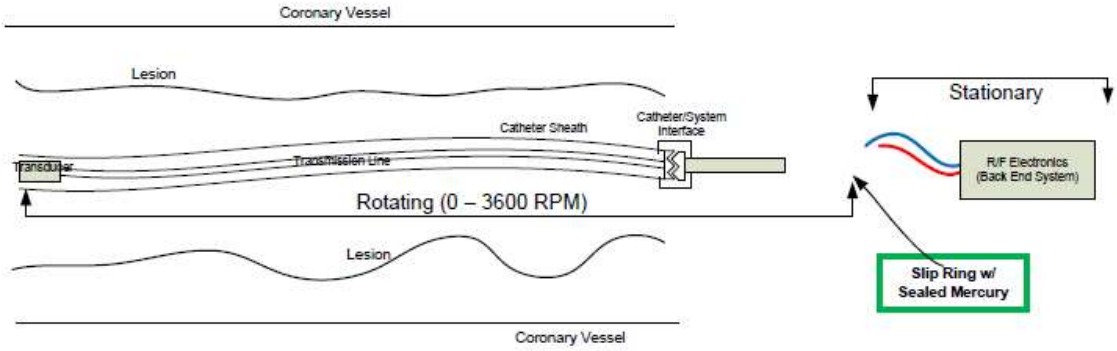
☒ other medical devices or other monitoring and control instruments than those in industry

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 ☐ PBD

3. Function of the substance: Mercury is used for the conduction path to provide a virtually noise free signal between a mechanically rotating ultrasound element (transducer) and stationary electronics. This connection passes both a high voltage RF signal at specific frequencies and a low voltage RF reflected ultrasound signal at specific frequencies. This connection is maintained as the transducer is rotated at varying rotational speeds (0 – 3600 RPM). See diagram below




4. Content of substance in homogeneous material (%weight): 450mgs/device

5. Amount of substance entering the EU market annually through application for which the exemption is requested: 9000mgs

   Please supply information and calculations to support stated figure.
   450 mgs x 20 units sold annually = 9000mgs

6. Name of material/component: Mercotac 205-H

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?**

The use of the mercury for the conduction path that provides a virtually noise free signal between a mechanically rotating ultrasound element (transducer) and stationary electronics*. This connection passes both a high voltage RF signal at specific frequencies and a low voltage RF reflected ultrasound signal at specific frequencies

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

The slip ring is the critical component in the mechanical imaging system that maintains electrical connection from the rotating transducer to the front-end ultrasound receive/transmit electronics contained within the imaging system. The slip ring is required to ensure transfer of ultrasound's RF signal in high-voltage, low current transmit mode, as well as low voltage, low current receive mode, while maintaining extremely low RF noise and not degrading the quality of the ultrasound signal itself for high rotational speed

## 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.)**

A closed loop material recycling system currently exists and is operating effectively.

**2) Please indicate where relevant:**

- ☒ Article is collected and sent without dismantling for recycling
- ☐ Article is collected and completely refurbished for reuse
- ☐ Article is collected and dismantled:
  - ☐ The following parts are refurbished for use as spare parts: _____
  - ☐ The following parts are subsequently recycled: _____
- ☐ Article cannot be recycled and is therefore:
  - ☐ Sent for energy return
  - ☐ Landfilled

**3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:**

- ☐ In articles which are refurbished _____
- ☒ In articles which are recycled 20x450mgs=9000mgs
- ☐ 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.**

Two commercial off-the-shelf alternatives to a mercury slip ring were reviewed as possible replacements. They are as follows:

1. Gallium alloy liquid metal – used as a direct substitute of mercury - available from Asian tool
2. Fiber brush technology – consisting of precious metal brushes and rings – available from Moog Components Group.

Review of the specifications for both of these potential alternatives has ruled out the use of these components in the HDi system. A comparison of the published specifications for the equivalent components is in the table below.

| Specification | Mercotac 205-H | Asian Tool A2S NM | Moog EC3848-6 |
|---|---|---|---|
| Technology | Mercury wetted | Gallium alloy | Fiber brush |
| Voltage | 0-250 VAC | 0-250 VAC | Low millivolt range to 100 VDC |
| Operating Speed | 0-3600 rpm | 0-1000 rpm | 0 - 10,000 rpm |
| Number of Rings | 2 | 2 | 6 |
| Temperature | 7°F - 60°F | 8°C-80°C | 50°C (120°F) over 1,000 rpm<br>80°C (175°F) up to 1,000 rpm |
| Current Rating | 4.0 Amps | 4.0 Amps | 1.0 Amps maximum per ring |
| Max. Freq. | 200 MHz | 20 MHz | No spec stated |
| Contact Resistance | <1mOhm | No spec stated | No spec stated |
| Rotation Torque (gm-cm) | 35 | 75 | No spec stated |
| Insulation Resistance | >25MΩ | >25MΩ | No spec stated |

## Asian Tool Gallium Alloy slip ring

Analysis was performed on the Gallium alloy solution from Asian Tool. As with the Moog alternative noted below, all products from Asian Tool were filtered for acceptability based on the following minimum performance requirements.

- current rating
- voltage rating
- 3600 rpm speed rating

Only the A2S NM meets the voltage and current requirements. However, the speed rating of 100 RPM is much less than the 3600 RPM required for the HDi

system. In addition, the Maximum Frequency rating of 20MHz for the Asian Tool A2S NM is much less than the required frequency for the HDi system.

Due to these concerns and analysis, ACIST Medical Systems, Inc. does not find the Asian Tool slip ring to be an acceptable candidate to replace the Mercotac slip ring.

## Moog Components Fiber Brush slip ring

As stated in 2nd questionnaire Exemption request No 2013-4 question number 5, the components available from Moog are not an acceptable candidate for replacement of the Mercotac slip ring. After further review, it was determined that the technology and components available from Moog has not changed in the last 5 years since the first exemption submission. Therefore, this solution is still not a candidate for legitimate replacement of the mercury slip ring.

Below is the response given to 2nd questionnaire Exemption request No 2013-4 question 5:

> *"An analysis was performed on the Moog Product Catalogue for Slip Rings. All products were filtered for acceptability based on the following minimum performance requirements.*
>
> - *current rating*
> - *voltage rating*
> - *3600 rpm speed rating*
>
> *Only the EC3848-6 meets the voltage and speed requirements and may be configured using multiple contacts to meet the current requirement, but the following specific concerns with the EC3848-6 arose during the assessment:*
>
> - *The published EC3848-6 spec sheets provide little data regarding RF performance. Only one parameter is listed that is of interest to an RF application. The 20 milliohms specification does not provide a complete picture due to being limited to the 5 rpm speed. This would have to be measured at operating speed, then the results would have to be shown in relation to frequency.*
> - *Other missing information that would be required to characterize an inline RF device includes: Return loss vs frequency; Loss vs frequency; and Noise vs frequency*
> - *The EC3848-6 does not have a 3 amp per channel capability (rated at 1 amp per channel). It would require three contacts for each leg of our signal path to handle our 3 amp signal. This would impact noise susceptibility due to the transmission line differences between the Mercotac coax transmission line and the Moog solid wire flying lead and solder terminal design. To accommodate this difference, a complete redesign of the electronics would be required, and the make-and-break electrical contacts would still be subject to pitting and the reliability issues mentioned above.*
> - *Routing the signal path through 6 individual slip rings will not only upset the critical balance of the catheter connection, but also expose the signal path to interference from the motor driver circuitry as well as the digital circuit boards*

*inside the PIM. The motor and digital circuit boards are located within millimetres of the slip ring.*

*Due to the above concerns and analysis, ACIST Medical Systems, Inc. does not find any Moog slip ring to be a candidate to replace the Mercotac slip ring."*

## Additional slip ring Analysis

Further research was conducted with the development of a custom gallium slip ring, in conjunction with Mercotac, using the current 205-H slip ring design and with substituting the mercury with gallium. The results of this study can be seen appendix A

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

See appendix A.

## 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.**

See appendix A.

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

The currently available technology does not indicate any viable solutions for the replacement of the mercury slip ring

## 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)? NO

☐ Authorization

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

☐ Restriction

☐ Annex XVII
☐ Registry of intrusions

☐ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: Not Applicable

**(B) Elimination/substitution:**

1. Can the substance named under 4(A)1 be eliminated?
   ☐ Yes. Consequences? _____
   ☒ No. Justification: See Appendix A
2. Can the substance named under 4(A)1 be substituted?
   ☐ Yes.
   ☐ Design changes:
   ☐ Other materials:
   ☐ Other substance:
   ☒ No.
   Justification: See Appendix A
3. Give details on the reliability of substitutes (technical data + information): See Appendix A.
4. Describe environmental assessment of substance from 4(A)1 and possible substitutes with regard to
   1) Environmental impacts: None. Product is fully recycled at end of life
   2) Health impacts: None. Mercury is completed encapsulated with no operator or patient access
   3) Consumer safety impacts: None. The HDi system is for use only in hospitals

⇨ Do impacts of substitution outweigh benefits thereof? Device will not operate reliably with the substitutes available.

Please provide third-party verified assessment on this: Not applicable

**(C) Availability of substitutes:**

a) Describe supply sources for substitutes: None Identified

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? Not applicable

**(D) Socio-economic impact of substitution:**

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

- ☒ Increase in direct production costs
- ☐ Increase in fixed costs
- ☐ Increase in overhead
- ☐ Possible social impacts within the EU
- ☐ Possible social impacts external to the
- ☐ EU Other: ___

⇨ Provide sufficient evidence (third-party verified) to support your statement: None Identified

## 9. Other relevant information

**Please provide additional relevant information to further establish the necessity of your request:**

No additional information can be provided at this time. ACIST will continue to research alternative materials that will meet the device performance requirements.

## 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:**

ACIST Medical provides the information in Appendix A and B, as well as the supporting documentation under confidentiality