EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate G - Sustainable Development and Integration
ENV.G.4 - Sustainable Production & Consumption

DIRECTIVE 2002/95/EC[1] ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (RoHS).

CHECK LIST FOR REQUESTS FOR ADDITIONAL EXEMPTIONS

Industry has sent to the Commission's services a number of requests for exemptions from the requirements of the RoHS Directive that are additional to those currently covered by the study and the stakeholder consultation. In most cases these are not substantiated by scientific and technical evidence. The proposed check-list will enable the Technical Adaptation Committee (TAC) to carry out a first screening of the requests received. Proposals that successfully pass the screening process will then be considered for a possible exemption.

Article 4(1) of Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment[1] provides 'that from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, PBB or PBDE.' The Annex to the Directive lists a limited number of applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4(1).

Adaptation to scientific and technical progress is provided for under Article 5 of the Directive. Pursuant to Article 5(1): "Any amendments which are necessary in order to adapt the Annex to scientific and technical progress for the following purposes shall be adopted in accordance with the procedure referred to in Article 7(2):"

Article 5(1)(b) allows the exempting of materials and components of electrical and electronic equipment from Article 4(1) if their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to therein is technically or scientifically impracticable, or where the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits thereof. <u>These terms of reference mean that the TAC cannot consider exemptions for any other reason, for example a justification based on increased costs.</u>

In order to allow the TAC to consider submissions for additional exemptions, the information in Table I should be provided as a minimum requirement. The request for submissions must fulfil the criteria of Article 5(1)(b). The information provided should be supported, as far as possible, with relevant technical and scientific evidence.

[1] OJ L 37, 13.2.2003, p. 19

TABLE I – CHECK LIST

PROPOSALS FOR FURTHER EXEMPTIONS FROM THE REQUIREMENTS OF ARTICLE 4(1) OF DIRECTIVE 2002/95/EC FOR SPECIFIC APPLICATIONS OF LEAD, MERCURY, CADMIUM, HEXAVALENT CHROMIUM.

Submitted by: ACIST Medical Systems (Manufacturer of advanced contrast injection technologies for the cardiac cath lab, hybrid operating room and radiology suite.)

Criteria	**Information:** **Please provide supporting technical and scientific evidence**
1. Please indicate the specific application for which the exemption is requested and indicate a precise and clear wording for the new exemption.	Electro-mechanical component containing mercury for specialized low noise, low/high voltage interconnect used in medical device applications for intravascular ultrasound imaging. (Category 8)
Please describe the material/component of the electrical and electronic equipment that contains the hazardous substance.	A high speed rotating electrical connector (slip ring) with an electrical conduction path that has sealed liquid mercury that is molecularly bonded to the contacts. (Reference: www.mercotac.com)
Please indicate the functionality of the substance in the material of the equipment.	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. This connection is maintained as the transducer is rotated at varying rotational speeds (0 – 3600 RPM). * **For more details see the flow diagram at the end of this application.**
Provide a detailed description of the application which explains why the restricted substance is currently required or used.	The slip ring is the critical component in the inherently 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. (Reference: www.svmii.com)
Please indicate the quantity of the hazardous substance present in the whole equipment (Kg).	There is one slip ring in the system which contains 450 mgs of mercury.
2. Please explain why the elimination or substitution of the hazardous substance via design changes of materials and components is currently technically or scientifically impracticable.	Typical silver-graphite brush slip rings introduce electrical noise into the signal being transmitted. Resistance through a typical slip ring is 10 - 20 milliohms. This design is incapable of providing a noise free signal that is required for the system to perform properly. Noise introduced into the system in this matter would be indistinguishable from actual reflected

Criteria	Information: Please provide supporting technical and scientific evidence
	ultrasound signal, rendering the image produced unusable for medical imaging. The slip ring in use offers a superior electrical connection because of the liquid Mercury which is bonded at a molecular level to the contacts – this component insures the reliability of the rotating system by providing a virtually noise free signal.
3. Please indicate if the negative environmental, health and/or consumer safety impacts caused by substitution are likely to outweigh the environmental, health and/or consumer safety benefits. If existing, please refer to relevant studies on negative impacts caused by substitution.	Substitution is not practical as mentioned above.
4. Please indicate if feasible substitutes currently exist in an industrial and/or commercial (please provide reference for the substitutes). If substitutes exist on the market, please indicate why they are not used. Please indicate in which applications they are used. Please indicate what efforts are being made by your company to develop alternative techniques. Please indicate if the alternative techniques will be available by 1 July 2006 or at a later stage. If not by that date, please indicate when you expect an alternative to be available?	Typical silver-graphite brush slip rings exist in industrial and commercial use. They are used to transfer power, control circuits, analog or digital signals including data and electrical signals from a stationary to a rotating structure. Examples include generators, motors, alternators, wind turbines, and radio telescope. A silver graphite brush slip ring introduces noise to the signal being transmitted for processing. In the application in question the signal generated must be virtually noise free to insure the equipment operates properly and provides an accurate picture of the area being imaged. The mercury slip ring connectors transmit with nearly zero electrical noise, thus the same connector can be used for power and signal transmission. Alternative design is not feasible that supports current system performance requirements for a low-noise, high-voltage transmit, and a low-voltage receive transmission at high rotational speed.
5. Please provide any other relevant information that would support your application for an additional exemption.	The manufacturer of the slip ring has completed reliability testing and recorded an average life of 828 days and over 2 million cycles before failure. For safety the device is designed to accumulate the mercury at the end of life in a containment area inside the body. In addition there are redundant sealing mechanisms to prevent external mercury leakage.

Additional guidelines

Explain the reasons why potential alternative materials, designs or processes are unsuitable with quantitative data wherever possible. If possible, provide photographs or diagrams to illustrate claims. Sources of information should be referenced where possible.

Please refer to the following system block diagram, indicating critical function performed by mercury-based slip ring for intravascular ultrasound medical imaging application: