1st Questionnaire Exemption No. IV.42 (renewal request)-Redacted

Date of response questions: 26 October 2018

1. Name and contact details

1) Name and contact details of applicant:

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1. **Are there other manufacturers of intravascular ultrasound imaging systems operating with high frequency above 50 MHz?**

   Yes, Boston Scientific OPTICROSS HD 60 MHz and Terumo Visicube 60 MHz.

2. **How do other manufacturers realise the conduction path between the rotating transducer and stationary electronics? Are there attempts for contactless signal transmission?**

   The information from other manufacturers is proprietary. Therefore, we cannot speculate about another manufacturer's technology.

   A contactless signal transmission does not seem feasible due to the sensitive nature of the imaging signal. Therefore, no resources have been applied to this.

   There are non-rotational IVUS available from other manufacturers; however, the image quality is at lower resolutions.

3. **Are there other diagnostic procedures than ultrasound imaging systems which provide comparable results?**

   No, there are no other procedures that provide comparable results to an ultrasound imaging system.

   Not to the resolution or imaging depth comparable to the capabilities of ultrasound technologies.

4. **In the summary of your exemption request, you mention key requirements to maintain system functionality, thereunder "*Max. Freq.: >80 MHz*". We assume that the maximum frequency will be up to 80 MHz (hence "Max. Freq.: ≤80 MHz")**

   Correct. Max. Freq.: ≤80 MHz

5. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, please provide details in respect of the following in relation to all EEE intravascular ultrasound imaging systems placed on the EU market through this exemption:

   a. **Please estimate possible socio-economic impacts, especially regarding health and employment in total, in the EU and outside the EU, should the exemption not be granted. Please detail the main sectors in which possible impacts are expected – manufactures of relevant equipment, supply chain, retail, etc.**

      The HDi System and Kodama catheter provides means to perform intravascular ultrasound (IVUS), a common technology for adjunctive imaging during percutaneous coronary interventions and monitoring progression/regression of coronary arterial disease. IVUS is a recognized method for determining if intervention of a stenosis lesion is necessary.

      Numerous clinical trials involving percutaneous coronary intervention and medical therapy have used IVUS imaging technology to evaluate primary and secondary clinical endpoints. Further, the scientific literature contains numerous reports that describe the safe and effective use of IVUS technologies for intracoronary imaging.

      The ACIST HDi System and Kodama catheter features, in addition to standard 40 MHz frequency, a 60 MHz frequency, which has the potential to provide better images in certain circumstances. The system also provides, in addition to the standard pull-back speeds of 0.5 – 2.0 mm/sec, faster speeds (up to 10 mm/sec), which reduce the amount of time required to acquire an image and thereby reduces the risk for ischemia.

   b. **Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. In this respect, please clarify if such a scenario would result in limitations to further use and maintenance of certain equipment (e.g. equipment placed on the market in the past[1], refurbished equipment, leased equipment, etc.).**

      Since we are not aware of a viable alternative design that would provide high reliability and equivalent performance, it is difficult to estimate the amount of waste generated through a forced substitution or rework process. If it is

[1] Article 4(4)(f) of Directive 2011/65/EU: EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

limited to the Slip Ring assembly, it would be the slip ring assembly times approximately a year of system sales in the EU.

c. **Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).**

d. **Please give estimations on the size of the EU market for all equipment expected to benefit from an exemption should one be granted.**

Summary

To achieve the axial resolution and depth of imaging field required for percutaneous transluminal arterial imaging within the ultrasonic frequency range the use of a rotating transducer is necessary.

Therefore, considering the lack of a viable alternative, the small quantity of the restricted substance by volume, the degree of protection surrounding the component, and the relatively small volume of devices with the components the exemption should be renewed.