



**Request for extension of exemption for the use of
mercury and cadmium in infrared detectors,
Annex IV of RoHS Directive 2011/65/EU**

20.01.2020

Exemption Request Form

Date of submission: 20 January 2020

1. Name and contact details

1) Name and contact details of applicant:

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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: **1c.**

Proposed or existing wording: **Cadmium and Mercury in infra-red detectors.**

Duration where applicable: **Maximum validity period of seven years**

Other:

3. Summary of the exemption request / revocation request

The application requests extension of exemption for the use of mercury and cadmium in infrared detectors for medical devices. Infrared measurement technology has various advantages over different techniques - it is highly sensitive, selective and very fast, allowing for real-time measurement of various substances, gases and fluids.

Infrared spectroscopy is a powerful clinical tool in medical diagnostics, due to its high specificity and sensitivity for disease detection and classification, allowing for low-cost, and rapid diagnostics platforms to prevent bottlenecks in healthcare workflows and subsequently time delays in patient care. Especially the MWIR (3-8 μm) and LWIR (8-14 μm) IR spectra are useful for diagnostics:

- Many gases have only in the MWiR significantly strong absorption features.
- The fundamental absorptions of many gases are much stronger in the MWIR than the overtone bands in the SWIR (e.g., CO₂ and CH₄).
- Separation of the absorption “fingerprints” of different molecules is easier in the MWIR and LWIR.

The most sensitive IR devices are based on photon detectors – i.e. compound semiconductors using II-VI, III-V and IV-VI compounds. The variable band gap Hg_{1-x}Cd_xTe (also called in short HgCdTe or MCT) has been undeniably the champion among the large variety of material systems, offering 2x up to 100x better detectivity levels in the MWIR and especially LWIR spectrum.

There are possible substitutes used in less demanding measurement applications – III-V compound semiconductor detectors. However, despite many years of development there have not been yet any commercially available detectors matching MCT detectors in terms of detectivity.

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:

Medical devices, specifically gas analysers and imaging devices used in non-invasive diagnostics.

Infrared radiation detection

Infrared radiation has been known about and used practically for over two centuries. The world around us and we ourselves are powerful sources of an invisible short wavelength (SWIR; 0.8 μm to 3 μm) middle wavelength (MWIR; 3 μm to 8 μm), long wavelength (LWIR; 8 μm to 14 μm) and very long wavelength (VLWIR; >14 μm) infrared radiation. The names and classifications of these subregions are conventions, and are only loosely based on the relative molecular or electromagnetic properties. Infrared radiation carries comprehensive information about objects that generate or interact with the radiation.

The first decades of the 21st century have brought rapid development in infrared (IR) technology and expansion of its applications in military (night vision, smart munitions, navigation, weapon detection), industrial (non-contact temperature measurements, communications, aerospace, medical diagnostics), environmental (atmospheric sounding, pollution control, meteorology, environmental monitoring), academic (e.g., astronomy) and medical diagnostics equipment.

Infrared spectroscopy

Infrared measurement technology has various advantages over different techniques - it is highly sensitive, selective and very fast, allowing for real-time measurement of various substances, gases and fluids [1]. The most common measurement technique is infrared spectroscopy. It covers a range of techniques, mostly based on absorption spectroscopy. As with all spectroscopic techniques, it can be used to identify and study chemicals. Infrared spectroscopy exploits the fact that molecules absorb specific frequencies that are characteristic of their structure. These absorptions are resonant frequencies, i.e. the frequency of the absorbed radiation matches the frequency of the bond or group that vibrates. The energies are determined by the shape of the molecular potential energy surfaces, the masses of the atoms, and the associated vibronic coupling.

Infrared spectroscopy is a very useful technique across the whole spectrum of infrared radiation. Nevertheless, Mid-IR gas sensing is especially important in the most popular industrial and medical applications. This is due to the fact that the most important gases are molecular gases and have strong rotational-vibrational absorptions in the Mid-IR spectral range.

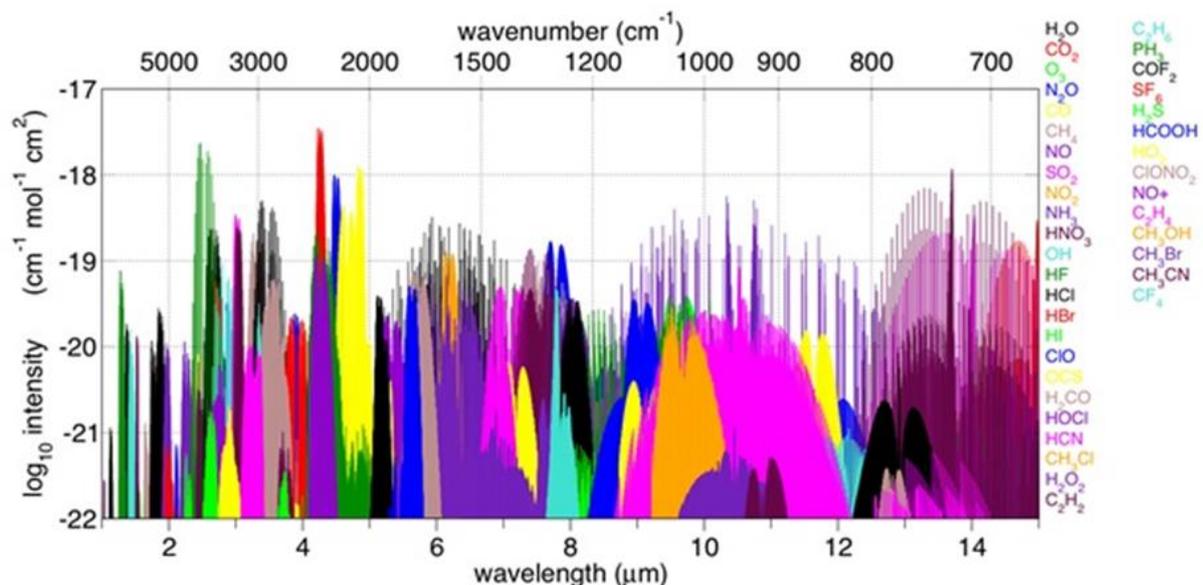
Mid-IR absorption is the usual measurement technique for CO₂. It is also most frequently used for hydrocarbons and quite often for CO measurements. **Sensitivity** is not the main reason to use Mid-IR gas-sensing devices. Other sensor principles may be more sensitive. But for industrial and medical applications **selectivity** is of equal importance. Due to the fact that the Mid-IR "fingerprint" of different gas molecules can be spectrally separated, a high degree of

selectivity can be achieved, and, e.g., false alarms by cross-interference to background gases are avoided. A further reason to favor Mid-IR gas sensing against other technologies is **stability**. For many applications, e.g., infrastructure installations, a sensor needs to have a long lifetime, stable response with almost no maintenance, giving some indication that it is working properly. This can be achieved with Mid-IR devices. [1]

From an application point of view, the Mid IR has the following advantages over Near-IR gas-measuring systems:

- Many gases have only in the MWiR significantly strong absorption features.
- The fundamental absorptions of many gases are much stronger in the MWiR than the overtone bands in the SWiR (e.g., CO₂ and CH₄).
- Separation of the absorption “fingerprints” of different molecules is easier in the MWiR and LWiR.

Figure 1 - Infrared absorption bands of different gases in the Mid-IR spectrum



Analysis of gases in medical applications

Infrared spectroscopy is a powerful clinical tool in medical diagnostics, due to its high specificity and sensitivity for disease detection and classification, allowing for low-cost, and rapid diagnostics platforms to prevent bottlenecks in healthcare workflows and subsequently time delays in patient care. The future implementation of IR spectroscopic techniques extends to, and may redefine, numerous stages of clinical management from screening all the way through to treatment monitoring.

Photonic technologies permit non-invasive detection of diseases. Examination of the gas components in exhaled breath has become a valuable diagnostic tool. It may reveal the status of your respiratory system. Additionally, trace breath components are markers for several diseases. Thus breath analysis has become an important field of medical research. Laser spectroscopy is one of the promising analytical techniques to measure trace gas concentrations in exhaled breath to the ppb to ppt range. A prominent example is exhaled NO

which indicates an inflammatory disease of the lungs, e.g., asthma. Other significant examples of monitoring gases in diagnostics are:

- ethane and acetylene as biomarkers for asthma, schizophrenia or lung cancer.
- methane as a biomarker for intestinal problems.
- CO can be a biomarker for respiratory infections and asthma.
- Ammonium is used as a biomarker for helicobacter pylori infections. These infections are responsible for stomach ulcers. Breath analysis diagnoses the disease in a non-invasive way sparing patients a disagreeable gastroscopy.
- CO₂ can be used for detecting Helicobacter pylori bacteria causing stomach ulcer. Breath analysis diagnoses such an infection in a non-invasive way replacing disagreeable gastroscopies. One of the recent examples of medical diagnostics systems using CO₂ monitoring is the Limax test introduced by Humedics - a non-invasive diagnostic test carried out at the patient's bedside. It is based on the metabolic turnover of ¹³C-labelled methacetin solution for intravenous injection and produces a quantitative measurement of maximal liver function capacity. This reveals liver metabolic function at cellular level in real-time, which correlates with liver disease severity and loss of liver volume following resection. [2]
- NO_x may be a biomarker for asthma and other pulmonary diseases. This new technology becomes more established for clinical applications. It is a cost-effective and non-invasive method of diagnosis and treatment monitoring.
- Surgical smoke occurs during the use of certain surgical instruments, such as lasers, drills or ultrasonic scalpels. It consists of several toxic and carcinogenic gases. Though detected in uncritical concentrations, these gases carry a health risk. Laser based spectroscopy offers a possibility to analyze even the lowest exposures.
- Child mortality is high among preterm newborn infants. They are often affected by free gas in lungs and intestines, which may lead to the breakdown of vital organs. The current diagnosis is based on X-ray radiography. According to a study a bed-side, rapid, non-intrusive, and gas-specific technique for in vivo gas sensing would improve diagnosis and enhance the babies' chance of survival. The detection method is based on laser spectroscopy.
- Formaldehyde has been used in consumer and industrial products since the beginning of the 19th century. Currently the annual formaldehyde production accounts for 21 million tons. About 50 % are processed as adhesives in pressed wood panels. In 2004 formaldehyde was classified carcinogenic by the International Agency for Research on Cancer. Since then formaldehyde concentrations have been strictly controlled in the production process as well as in the finished product. Laser-based measurement systems are required to detect the maximum levels of 0.01 ppb (USA) and 2 ppb (EU).

Infrared spectroscopy can be also a great tool in many other diagnostics fields:

- analysis of biofluids - spectroscopic biofluid analysis could be used to analyse various biomarkers found in s serum, plasma, whole blood, sputum, bile, amniotic fluid, cerebrospinal fluid, urine, saliva, and tears.
- analysis of tissues and cells - Spectral histopathology permits to profile chemically complete clinical sample sections in a nondestructive manner without the requirement for stains, antibodies, and secondary labeled reagents.

The obtained detection limits of gases related to selected diseases biomarkers with the use of CEAS sensors are summarized in Table 1. These sensors used HgCdTe photodiodes.

Table 1. Summary of achieved detection limits for selected biomarkers.

Wavelength [μm]	Biomarker	Detection Limit [ppb]	Uncertainty [%]	Type of Applied Laser
5.2630	NO	30	0.7	QCL
4.8716	OCS	0.9	2.6	Tunable laser system
3.3481	C ₂ H ₆	0.3	0.2	Tunable laser system

Infrared sensors

There is a large variety of MIR sensors based on incoherent and coherent radiation sources. These are mostly the Non-Dispersive InfraRed (NDIR)-based sensor systems, but also FTIR spectrometers, Fabry-Pérot interferometers (FPI) and microspectrometers that use broadband and tunable infrared emitters [1].

The key components of most IR systems are infrared detectors that convert the invisible radiation flux into easily measurable signals, typically electrical ones. The devices are characterized by a variety of parameters. The most important is the detectivity, which is the normalized signal to noise ratio and its spectral and time response.

Detectors of optical radiation are usually categorized in one of two groups:

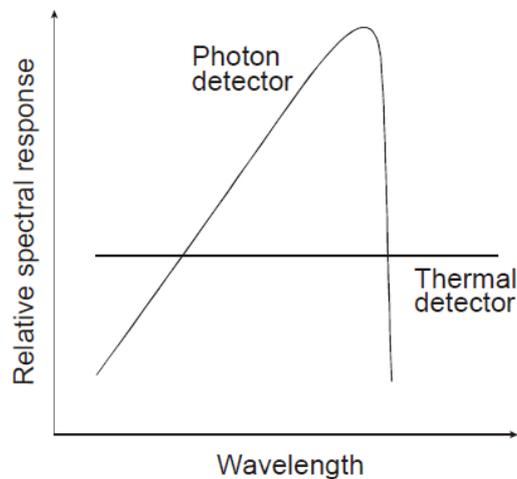
- thermal detectors
- photon detectors (photodetectors).

Thermal detectors sense the heat generated by the absorbed radiation, so their operation is a two-step process: the conversion of radiation energy into heat, followed by the conversion of heat energy into the energy of an electrical signal. The signal does not depend upon the photonic nature of the incident radiation but upon the radiant power, and is generally wavelength-independent.

Being unselective, they can be used over an extremely wide range of the electromagnetic spectrum, from X-rays to ultra-violet, visible, IR, and microwaves. The room temperature operation of thermal detectors makes them lightweight, rugged, reliable and convenient to use. However, thermal detectors are characterized by moderate sensitivities and suffer from a slow response which prevents their use in demanding applications. Neither sensitivity nor speed of response can be improved significantly with cooling.

The operation of photodetectors is based on optical generation of charge carriers in semiconductor absorbers followed by a collection of the carriers at contacts. This makes it possible to achieve both high sensitivity and a fast response.

Figure 2 – Relative spectral response for a photon and thermal detector



Photodetectors are traditionally categorized into

- photoconductive,
- photovoltaic,
- photoelectromagnetic,
- and other types of detectors,

depending on their design and the principle by which optically generated carriers are sensed.

The ultimate sensitivity of any type of infrared photodetectors is determined by the ratio of absorption coefficient to the thermal generation rate of charge carries [3].

The direct band gap narrow gap semiconductors are the best materials for the HOT photodetectors. The II-VI, III-V and IV-VI compounds have been the material systems used in practice. They include fixed band gap binary alloys, tunable band gap ternary semiconductors, and band gap engineered superlattice materials. The binary compounds can be used for applications that require optimum performance at the spectral range corresponding to band gap of the material. Availability of binary compound is very limited, especially in the long wavelength (8-14 μm) (LWIR) range of IR spectrum. Therefore, the use of tunable band gap ternary and quaternary is necessary for many applications.

The variable band gap $\text{Hg}_{1-x}\text{Cd}_x\text{Te}$ (also called in short HgCdTe or MCT) has been undeniably the champion among the large variety of material systems [12]. Three key features condition its position:

- Wide band gap tunability by composition (CdTe to HgTe ratio) changes with a weak dependence of HgCdTe lattice constant. It allows for growth of defect-free complex semiconductor heterostructures consisting of different composition layers which are necessary to optimize operation of the IR detectors at any wavelength within an extremely wide spectral range of 1 to 30 micrometers and temperatures 60 to 300 K. This also facilitates fabrication of multicolour and avalanche photodiodes.
- Favourable inherent charge carriers generation and recombination mechanisms leading to the best Signal-to Noise (S/N) performance at high operating temperature.
- Good charge carriers transport properties which ensures an efficient and fast collection of photogenerated charge carriers and results in a high responsivity and fast response of HgCdTe-based devices.

a. List of relevant categories: (mark more than one where applicable)

- | | |
|----------------------------|---------------------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 7 |
| <input type="checkbox"/> 2 | <input checked="" type="checkbox"/> 8 |
| <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 10 |
| <input type="checkbox"/> 5 | <input type="checkbox"/> 11 |
| <input type="checkbox"/> 6 | |

b. Please specify if application is in use in other categories to which the exemption request does not refer:

cat. 9 - Monitoring and control instruments including industrial monitoring and control instruments

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

Exemption for other categories (i.e. in-vitro-diagnostics, monitoring and control instruments in industry,) is still valid until 21.07.2023 and 21.07.2024 respectively.

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: **Mercury and Cadmium are the basic components of mercury cadmium telluride (HgCdTe), the unique variable band gap semiconductor used for infrared (IR) photodetectors.**

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

Cadmium and Mercury are components of mercury cadmium telluride (MCT or HgCdTe), which is deposited on top of the Gallium Arsenide surface, creating infrared detector chip. Typical MCT layer has only thickness.

Concentration of mercury within a typical infrared detector chip - ~0,7% of chip weight.

Concentration of cadmium within a typical infrared detector chip - ~0,5% of chip weight.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: **Mercury - 0,003g, Cadmium - 0,0023g**

Please supply information and calculations to support stated figure.

No accurate data is available. It is estimated that yearly global production of MCT detectors for commercial application is around 10.000 pcs/year. Out of this only 1-2% of detectors are currently used for medical applications. Weight of a single pixel detector chip is around 0,005 g ($5 \cdot 10^{-3}$ g). Typical detector comprise 0,0000314g ($3,14 \cdot 10^{-5}$ g) of mercury and 0,0000235g ($2,35 \cdot 10^{-5}$ g) of cadmium.

Therefore the total global amount of mercury in MCT detectors is around 0,3g, while cadmium - 0,23g, out of which in medical application it is 0,003g of mercury and 0,0023g of cadmium.

6. Name of material/component: **Infrared detector chip made of mercury-cadmium telluride**

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 two RoHS-regulated substances, Mercury and Cadmium, are the basic components of Mercury Cadmium Telluride (HgCdTe), the unique variable band gap semiconductor used for fabrication of infrared (IR) photodetectors.

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

The variable band gap $\text{Hg}_{1-x}\text{Cd}_x\text{Te}$ (also called in short HgCdTe or MCT) has been undeniably the champion among the large variety of material systems [12]. Three key features condition its position:

- Wide band gap tunability by composition changes with a weak dependence of HgCdTe lattice constant on composition. It allows for growth of defect-free complex semiconductor heterostructures consisting of different composition layers which are necessary to optimize operation of the IR detectors at any wavelength within an

extremely wide spectral range of 1 to 30 micrometers and temperatures 60 to 300 K. This also facilitates fabrication of multicolour and avalanche photodiodes.

- Favourable inherent charge carriers generation and recombination mechanisms leading to the best Signal-to Noise (S/N) performance at high operating temperature.
- Good charge carriers transport properties which ensures an efficient and fast collection of photogenerated charge carriers and results in a high responsivity and fast response of HgCdTe-based devices.

The dark current of the state of art HgCdTe photodiodes is described by the Rule 07 [13].

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.)

Mid-IR sensors, as professional laboratory equipment, are disposed of in a controlled system.

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

Mercury - 0,003g,
Cadmium - 0,0023g

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

The III–V semiconductors are alternatives for the use of RoHS regulated substances in fabrication of the infrared photodetectors [14-15]. InSb and InAs were the first III-V compounds discovered in the 1950s and used for photodetectors with the long cut-off wavelength of ~ 5.5 and ~ 3.2 μm , respectively at 77 K. The materials are characterized by a dark current much larger compared to that of HgCdTe of the same band gap. This is presumably associated with the Shockley-Read (SR) thermal generation due to some departure of the semiconductors from perfect crystallinity. It is interesting to note that SR generation in InSb value has not been improved through the last 50 years. The use of the InSb and InAs is limited by the fixed cut-off wavelength of the materials. InGaAs and InAsSb are the variable band gap alloys, whose long cut-off wavelength can be tuned by changing the composition in the range from ~ 1 to ~ 3.4 and ~ 3.4 to ~ 20 μm , respectively. The InAsSb alloys are characterized by the SR recombination time of ~ 400 ns similar to that of InSb, several orders of magnitude shorter compared to HgCdTe. The longest SRH-value for III-V materials equal to ~ 200 μs was found for SWIR lattice-matched epitaxial InGaAs ternary alloy on InP substrate, with cut-off wavelength of 1.7 μm [15].

The SR generation of the dark current occurs mostly in the depletion region of photodiodes. Therefore, the SR related dark current can be suppressed to a large degree by the use of the devices with neutral narrow band gap absorber. This can be achieved by the use of devices free of depletion layer such as the photoconductors or photoelectromagnetic devices consisting only of an absorber layer, and the three layers minority carrier photoconductors e.g. nBnn [14-19]. Another solution is photodiodes with a wide gap unipolar barriers in which depletion layer is located in the wide gap materials where SR processes are highly suppressed. The barriers also block carriers thermally generated outside the absorber layer. The dark current in such devices is only the diffusion current generated in the neutral absorber by the less intensive SR, Auger, radiative and other mechanisms which highly improve the performance.

The last two decades have brought rapid development of detectors based on artificial superlattice semiconductors, initially the InAs/GaSb [20-24] and then InAs/InAsSb [14,15,25-27]. Theoretical consideration have promised better performance of the SL-based IR photodetectors compared to the HgCdTe counterparts, mostly due to the highly suppressed Auger thermal generation [20-21]. Actually, the dark current in the SL devices appeared to be dominated by a large SR generation rate. The more successful are Ga-free InAs/InAsSb SL devices due to reduced SR generation [25-29]. As in the case of InAsSb alloy detectors, sophisticated detector architecture is a must to prevent the formation of a spatial charge in a narrow-gap absorber, where the SR generation could be very large. Another source of excessive dark current are dislocations due to mismatches between the substrates and regions of the detector heterostructure. An additional issue is a short diffusion length in the MWIR and LWIR absorber which reduce the responsivity of the SL devices. The problem can be solved using cascade detectors with stacked multiple photovoltaic cells connected in series [30].

Generally, the expected benefits of new technologies have not been fully achieved in practice. It should be noted that SR generation does not have fundamental nature so the performance

of the SL device can be improved by refinement of the material growth technology leading to reduction of defects in the heterostructures.

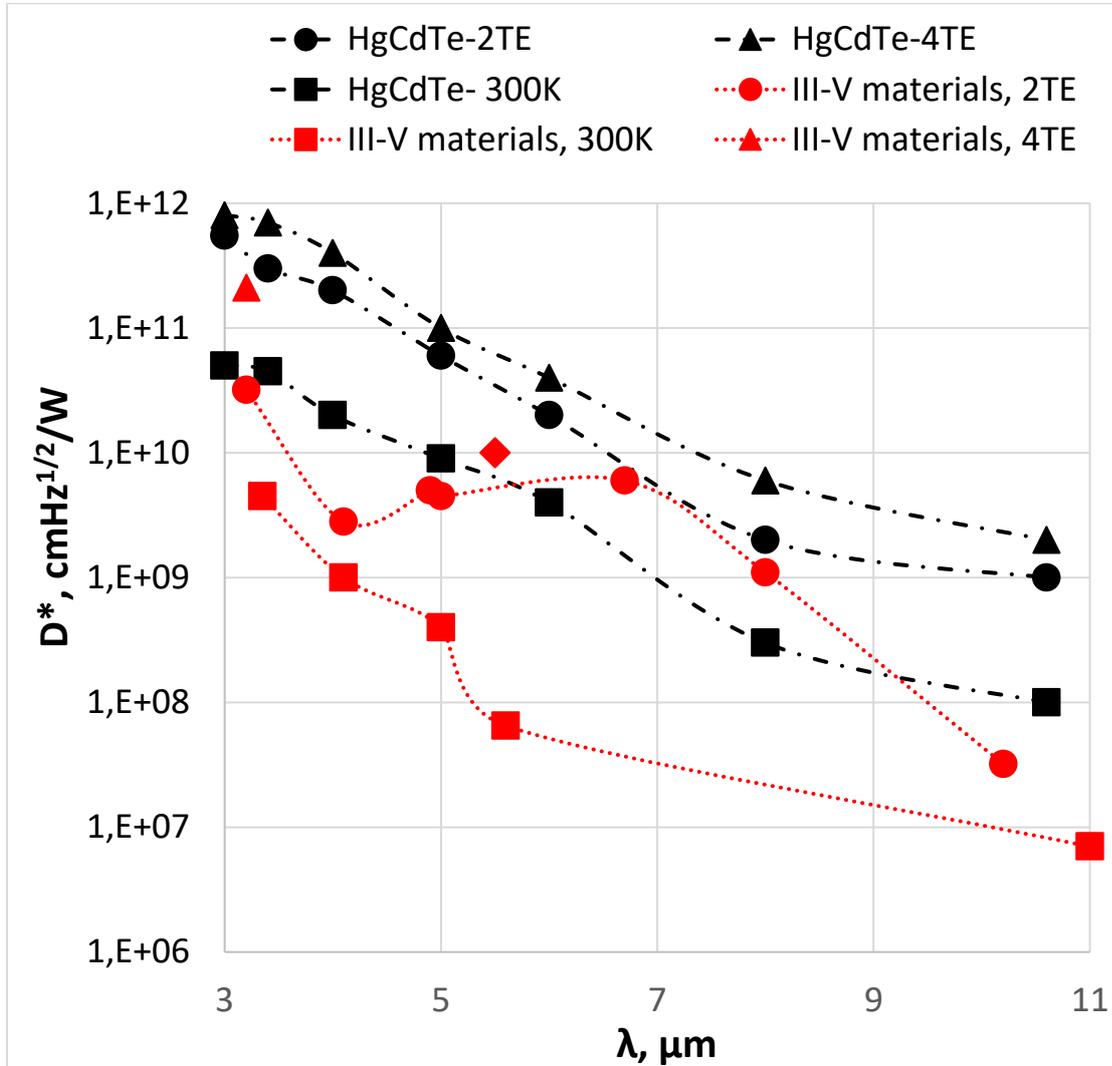
The III-V semiconductors also have significant disadvantages that hinder their widespread use:

- The lack of variable band gap alloys with a composition-independent lattice constant, which makes the fabrication of heterostructure devices very difficult.
- No universal matched substrates exist.
- Very complex crystal defect structure
- Large concentration of uncontrolled native and foreign dopants which results in unfavourable charge carriers generation and recombination mechanisms that reduce the Signal-to Noise (S/N) performance.

At present HgCdTe remains the material of choice for demanding applications [12,15].

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

Figure 3 – Comparison of commercially available detectors of MCT (HgCdTe) and III-V materials (logarithmic scale)



Despite years of development there are no commercially available III-V detectors that would match the performance levels of MCT detectors. Detectivity level of III-V detectors is still significantly lower than mercury-cadmium sensors – even up to 2 orders of magnitude (MCT detectors are 100x better than III-V detectors at some wavelengths, especially at LWIR spectrum).

Using commercially available detectors from III-V materials (due to their D^*), detection limits for biomarkers (from Table 1) are about one order of magnitude worse.

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.

For many years, Intensive efforts have been underway for several decades to replace HgCdTe [14].

Theoretical analyses, literature studies and results obtained so far indicate the possibility of replacement of HgCdTe with the substitutes. Until now, the growth of complex heterostructures for the short, middle and long-wavelength detectors on GaAs substrates has been mastered.

This allows the production of detectors monolithically integrated with immersion microlenses, increasing sensitivity of the device by an order of magnitude. The most important results have been the development of uncooled and Peltier cooled devices [11, 31-43]:

- Short-wavelength MOCVD grown InGaAs photodiodes with cut-off wavelength from 1.7 to ~2.8 μm with detectivity ~2 x less than for HgCdTe devices
- MBE-grown InAsSb middle-wavelength photodiodes from 3.4 μm to 6 μm cut-off wavelength with detectivities ~3x less than for HgCdTe devices. The devices have already found some practical applications in less demanding chemical analyzers.
- Long (>10.6 μm) photoconductors based on MBE grown InAs/InAsSb superlattices with detectivities close of better compared to those of HgCdTe. The use of this device is limited, but the result proofs the feasibility of other types of the high quality long wavelength devices.
- The first cascade photodiodes.

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

Establishment of substitute to the RoHS regulated substances would require:

- Improved design of the InAs/InAsSb detector heterostructures taking into account unavoidable limitations of the MBE and MOCVD epitaxial techniques
- Refinement of the growth procedures to reduce concentration of residual uncontrolled dopants, SR centers and density of dislocations in the the InAs/InAsSb SL-based detector heterostructures
- Growth and characterization of the heterostructures for several types of photodetectors.
- Processing, packaging and characterization of the several types of photodetectors for medical applications
- Iterative corrections of the design and growth procedures of detector heterostructures.
- Development of fast and sensitive devices with the use of plasmonic enhanced absorption of IR radiation

The abovementioned stages require a lot of effort in development and refinement of epitaxial growth techniques – where actual results are visible in nanoscale and are quite difficult to be measured. The applicant estimates that it would take another 5-7 years to introduce new type of III-V detectors with detectivity and reliability levels of MCT.

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**

Authorisation

SVHC (**Cadmium**)

Candidate list (**Cadmium**)

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: **N/A**

Concentration of cadmium in articles (infrared detectors) is below 0,1% w/w, and the annual amount of cadmium in infrared detectors for medical application is less than 1g.

(B) Elimination/substitution:

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

Yes. Consequences? **Elimination of MCT IR detectors would lead to significant deterioration of the accuracy of measurement and control devices used for medical applications.**

No. Justification:

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

Yes.

Design changes:

Other materials:

Other substance: Only for less demanding applications.

No.

Justification: **There has not been yet any reliable substitutes for MCT detectors, offering comparable levels of detectivity at room temperature in the MWIR and LWIR IR spectrum.**

3. Give details on the reliability of substitutes (technical data + information):

See point 6B.

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:

Ad 2) and 3)

There is no direct exposure of cadmium or mercury on users of control and monitoring equipment using infrared detectors. Both cadmium and mercury are bound by covalent bonds within the semiconductor material. Mercury cadmium telluride material is then itself hermetically sealed during packaging. It is highly unlikely that detector is handled, mechanically treated or otherwise modified by any user in such a way that cadmium or mercury could be released.

Also exposure to cadmium or mercury from infrared detectors released to the environment as a consequence of end-of-life or recycling operations is highly unlikely due to very small amount of these substances introduced to the market annually in infrared detectors (less than 1g annually).

⇒ Do impacts of substitution outweigh benefits thereof?

Please provide third-party verified assessment on this:

(C) Availability of substitutes:

- a) Describe supply sources for substitutes: **N/A**
- b) Have you encountered problems with the availability? Describe: **N/A**
- 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? **N/A**

(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

Negative impact on development of new technologies

Infrared spectroscopy is still a novel technique in medical diagnostics, although there is a variety of new R&D projects aimed at introduction of fast, accurate sensors allowing real-time measurement and monitoring of various biomarkers and diagnostics of many diseases.

According to Photonics 21 [45] the European population ages increasingly: the number of people older than 65, relative to those in the working age, is assumed to increase by a factor

of two by 2045. Since age is one major factor for an increased probability of becoming ill, a significant increase of corresponding illnesses like type 2 diabetes, many cancer subtypes like breast cancer in females and prostate cancer in males as well as lung cancer for both sexes⁴¹, dementia and macular degeneration are concomitant effects.

The future implementation of IR spectroscopic techniques extends to, and may redefine, numerous stages of clinical management from screening all the way through to treatment monitoring. There is a growing need for faster, more accurate, non-invasive diagnostics tools that will help diagnose various diseases at earlier phases or improve patient condition after medical interventions at hospitals. Development of new medical applications will lessen the burden on the European healthcare system, which already consumes more than 10% of the EU GDP, and with ageing population it will require substantially more spending.

Elimination of MCT detectors will undoubtedly slow development of new diagnostics tools, as any substitute substance IR detectors are at least 3x less sensitive than MCT.

Negative impacts on European Union economic growth

According to Photonics21 market report [44] European industry is already among the global leaders in the healthcare market, which is growing with double-digits. The total market volume of the segment in 2015 was €33.8 billion. Photonics for Healthcare is assumed to reach around €50 billion worldwide by 2021. Accordingly, it is not only one of the largest markets among photonics, but also one of the more rapidly expanding sectors. With its rich innovation landscape formed by traditional companies, start-ups, universities and research institutions, Europe has a unique opportunity to secure a prominent role and lead the corresponding markets if the challenges are met accordingly in the next few years.

EU has currently leading position in the market of MCT detectors production for commercial (medical, monitoring and control instruments), with more than 50% of the market share, which is also growing very fast (>10% growth in recent years). Moreover, MCT detectors are critical components for many EU companies producing measurement and control equipment for many applications (industrial, medical, scientific, etc.). There is no accurate data on the global market for MCT detectors in commercial applications. It is estimated that its value is around 30-50 million EUR. However, the value of the market of measurement and control instruments using MCT detectors is at least 10x larger.

Withdrawal of MCT detectors would undermine the position of EU companies in the global market, especially in comparison to companies from other regions, where using MCT detectors is not prohibited.

Possible social impacts external to the EU

Social impacts external to the EU will be significantly less severe as there is no prohibition of use of MCT detectors in medical diagnostics instruments outside of 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:

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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:
