Exemption Request Form – NON-CONFIDENTIAL

Date of submission: 8th October 2021

1. Name and contact details

1) Name and contact details of applicant:

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Name:	Jim Richard	E-Mail:	jrichard@werfen.com
Function:	Director Quality Engineering	Address:	180 Hartwell Road, Bedford, MA 01730, USA

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

Company:	Intertek Health, Environmental & Regulatory Services	Tel.:	+4520577975
Name:	Torben Norlem	E-Mail:	Torben.norlem@intertek.com
Function:	Chief Counsel	Address:	Vesterbrogade 74, 1620, Copenhagen, Denmark

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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: *Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric*

electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood.

Duration where applicable: 24 months

☐ Other: _____

3. Summary of the exemption request

Instrumentation Laboratory is a leading manufacturer of equipment which analyses critical care analytes in whole blood, used in hospitals and laboratories in all world markets. We operate under ISO 14001 and are committed to meeting European and country specific environmental requirements.

Instrumentation Laboratory manufactures the GEM Premier ChemSTAT diagnostic medical analyzer for the entire EU Market. These instruments are used to measure the blood of patients and provide clinicians with accurate measurements of specific analytes vital to medical diagnosis and patient treatment. The reported analytes include pH, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, hematocrit, creatinine, Blood Urea Nitrogen (BUN) and tCO_2. The GEM Premier ChemSTAT enables rapid risk stratification and prioritization of acutely ill patients in the Emergency Department and other point-of-care locations. Expedited time to treatment for critically ill patients including COVID-19 patients is essential to improving patient outcomes.

Instrumentation Laboratory is diligently working to remove lead from all products offered to the EU. Compared to other GEM platforms, GEM Premier ChemSTAT has minute quantities of lead. As the newest product in the GEM family, GEM Premier ChemSTAT contributed less than 0.5 kg of lead annually in 2020.

Due to the current COVID-19 pandemic, Instrumentation Laboratory has experienced increased analyzer and cartridge demand due to the critical role of blood gas analysis in the management of hospitalized patients with COVID-19. Therefore, the RoHS project for the latest GEM platform – GEM Premier ChemSTAT (contributing the least amount of lead) has been delayed. With the increase in demand of GEM platform cartridges and the impact of worldwide supply chain issues for GEM cartridge components, manufacturing efforts have been focused on meeting hospital needs. Due to the necessary shift in focus to meet customers' high demands, fewer GEM ChemSTAT RoHS sensor cards and cartridge were manufactured for research and development testing.

The above-mentioned delays were of particular impact for GEM Premier ChemSTAT due to additional technical challenges unique to this platform that require additional due diligence. GEM Premier ChemSTAT introduces two new sensors and associated reagents.

The addition of Creatinine and Blood Urea Nitrogen (BUN) measurements to GEM Premier ChemSTAT aid in the diagnosis, monitoring and treatment of renal dialysis and metabolic diseases. The increased complexity of Creatinine and BUN sensor designs

make these new sensors more difficult to manufacture than sensors on other GEM platforms. For instance, Creatinine requires a combination of a 3-enzyme formulation versus a single enzyme formulation for Glucose and Lactate. Similarly, the BUN sensor is manufactured using 4 layers of polymers and enzyme, as compared to the standard 2-layer construction on other GEM platforms.

In addition to two new complex sensors, the GEM Premier ChemSTAT was designed with unique reagents requiring more complex sensor calibration process (3-point calibration on GEM Premier ChemSTAT vs. 2-point calibration on other GEM platforms). These unique features have a higher likelihood to be impacted with the sensor card resin change to become RoHS compliant. The GEM Premier ChemSTAT analyzer was commercially released in December 2019 and are primarily deployed in the EU at several hospital locations including oncology and emergency departments (ED). There are limited clinical data available on this newest product using the current production resin, therefore additional effort is required to ensure the analytical performance claims (Method Comparison, Precision, Use Life and Shelf Life) are met with the sensor card resin change.

CMR 1345 has been selected as a RoHS-compliant sensor card resin candidate for GEM Premier ChemSTAT, as shown in the Analytical testing summary (Appendix B). Instrumentation Laboratory is diligently testing CMR 1345 to ensure this sensor card resin change does not negatively impact the analytical performance characteristics, patient safety or effectiveness of the device. However, multiple RoHS-compliant sensor card lots still need to be manufactured and tested for verification studies. As shown in the feasibility testing summary (Appendix B), RoHS CMR 1345 has met analytical requirements and is considered the primary resin candidate. Based on these data, there is high confidence in the RoHS sensor card resin regarding Creatinine and BUN performance. The project to implement a RoHS-compliant sensor card resin has exited feasibility with a clear and predicable path to start verification studies. Therefore, Instrumentation Laboratory is requesting the exemption in this application to execute verification studies to implement the RoHS-compliant sensor card resin CMR 1345 on GEM Premier ChemSTAT.

We respectfully request that this application for an exemption be approved, as the sensor card is the critical part of the GEM Premier ChemSTAT analyzer, where all the electrochemical measurements of blood take place. Without this submission being approved, the supply of point-of-care (POC) GEM Premier ChemSTAT analyzers that support hospitals and laboratories in the EU will be jeopardized, negatively impacting several hospitals in the EU Health Care Sector. If an exemption is not granted, it would require a delay in patient care as all hospitals using the GEM Premier ChemSTAT would need to convert to an alternate technology. This would require additional training on competitive analyzers, elevating risk of mistakes which may pose a threat to patient safety, thereby increasing cost to all EU Heath Care currently using the GEM Premier ChemSTAT. Other competitive solutions on the market in the EU for POC creatinine

measurements are either single use (generating more waste) or require burdensome consumables with different on-board stabilities and refrigerated storage conditions. Moreover, the competitive analyzers need hands-on time to be maintained and/or troubleshooted as often as daily or weekly basis. Conversely, the GEM Premier ChemSTAT is a self-contained system requiring very little operator interaction. This additional attention needed for competitive analyzers requires specialized service personnel, which can cause significant downtime, prolonging time to results/treatment and negatively impacting patient care while significantly increasing hospital costs. Additional operator training would be required on competitive analyzers, thereby improving opportunities for mistakes which may jepondarize patient safety. Furthermore, these competitive analyzers do not offer fully enclosed analytical systems leading to increased biohazard risks.

In addition, the results of the Life Cycle Assessment show that the Current GEM Premier ChemSTAT Sensor Card performs better in environmental terms than the planned alternative. Meanwhile, we have an active project plan and are confident in our ability to successfully complete this project to the timeline included here.

Instrumentation Laboratory kindly invites the European Commission and the EU Member States to review this application for an exemption under RoHS and the supporting documentation accompanying the application. We hope for a constructive and positive review process and we will proactively support all request and inquiries that Competent Authorities and relevant Stakeholders may have in this respect.

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: The Sensor Card Used in Cartridges for the GEM Premier ChemSTAT®.

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

☐ 1	☐ 7
☐ 2	X 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: N/A

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

3. Function of the substance: Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood

4. Content of substance in homogeneous material (%weight): 6.5%

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

Estimated total amount of lead contributed to the EU in 2022 by sensor card for GEM Premier ChemSTAT analyzer = 0.5-10 kg.

6. Name of material/component: Electrochemical sensor cards composed of Polyvinyl chloride (PVC). Please refer to specific information provided below in point b).

Environmental Assessment: Appendix F includes a report providing an analysis of the current GEM sensor card and identified alternatives from a Life Cycle Assessment perspective.

Intertek has carried out an environmental Life Cycle Assessment (LCA) of Lead and an alternative for Lead used or potentially used in sensor cards.

Currently Lead is used in the product. The alternative considered to replace Lead in the product consists of a combination of three substances, _. Lead is used as an additive on its own, in contrast to the other three additives, which must be used in a combination of all three to match the functional performance of Lead.

The LCA was performed with guidance from ISO 14040: Environmental Management – Life Cycle Assessment – Principles and Framework and ISO 14044: Environmental Management – Life Cycle Assessment – Requirements and Guidelines [1]. A separate full LCA report provides a complete set of LCA methodological details as required by the ISO standards, summarised here.

The LCA study evaluates the environmental impacts at various stages of the life cycle of the four additives. Material and energy inputs and outputs are identified through the life cycle of the substances, summed up, and converted to measures of environmental impact. This permits quantified data analysis of environmental advantages and identification of opportunities to reduce environmental impacts.

The primary goal of the LCA study is to provide an analysis of the environmental impacts of the substances. The functional comparison is Lead additive versus the combination of -.

One kilogram of sensor card polymer would typically contain:

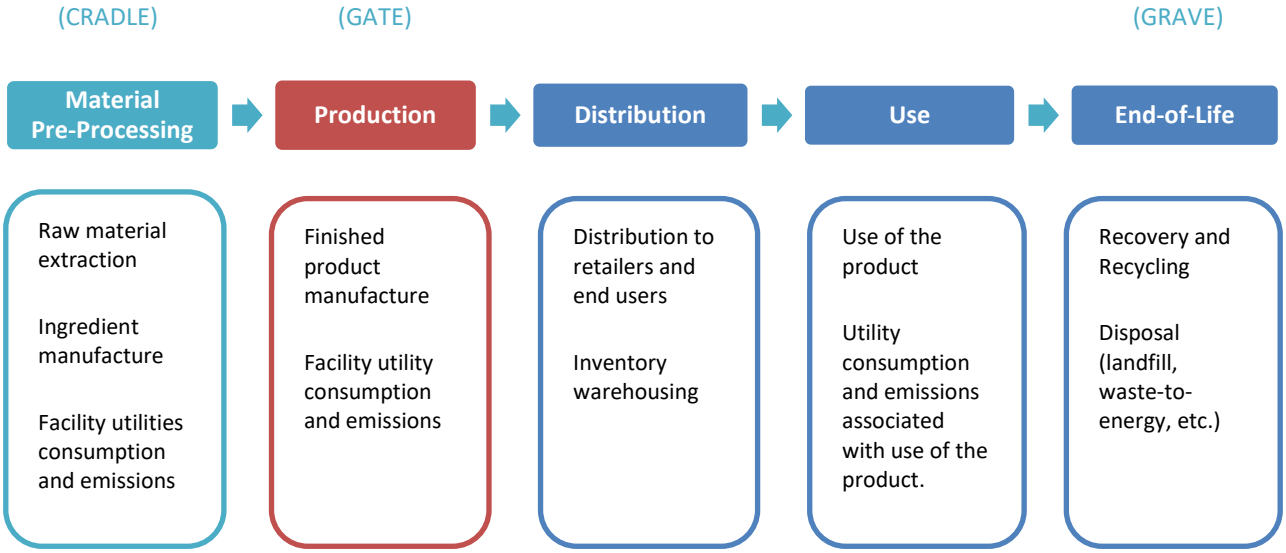
- Lead 0.98 g

or

- _
- _
- _

The relevant substances have been modelled in the weights they would appear in the real product as per above. In LCA terms, the functional unit is the amount of substance (or substances) required in one kilogram of sensor cards, and the reference flows are the amounts shown above.

The LCA system boundary for the additives includes cradle-to-grave life cycle stages. This boundary considers raw material extraction, pre-production processes, production, transport and final disposal of the product (the additive). The card itself, and operation of the unit such as electricity use during blood analysis, are not included.



Intertek utilised SimaPro 9.11 LCA software [6] to carry out the LCA, with data primarily from the Ecoinvent 3.6 database [2]. The data in these built-in resources were applied for commonly used materials, products and processes when internationally accepted generic information or secondary data is required for the study. The Ecoinvent 3.6 database is one of the most comprehensive and reliable resources for LCA data available globally. Instrumentation Laboratory provided the additives that are categories as one material or substances, minimal assumptions were made on the composition of the additives.

While raw material and sub-component data sets within the Ecoinvent 3.6 database [2] typically include raw material extraction, transport, infrastructure, emissions, waste and energy use, they do not include any packaging and/or palletizing that is applied to sub-components in their

transport to the finished product manufacturer. All input information is assumed to be as accurate as possible at the time of the study. For materials not being present in the Ecoinvent 3.6 database [2] the following assumptions have been made:

_:

A complete chemical formula for the synthesis of _ including co-products does not exist in the Ecoinvent 3.6 database [2]. Therefore the substance was modelled by being built up from its chemical building blocks. _

The weight has been calculated based on the relation of the molecular weights in relation to the total molecular weight of the _. The amount of energy (electricity, medium voltage, and natural gas) needed for the synthesis of _ has been assumed to be the same as the amount of energy used for the production of _ as per below.

_:

_ is a rare mineral that does not exist in the Ecoinvent 3.6 database [2]. Data from a study from the European Union [3] has been used to model _:

Table 4. Input data of the production of 1 tonne of . Elaboration of data provided by Kisuma.

Parameters	Unit	Values
Electricity consumption	MWh	1.4
Natural gas consumption	MWh	3.56
Water consumption	m^3	46
	t	0.66
	t	2.92
	t	0.49
	t	0.52
	t	0.30
	t	0.40

Table 5. Output data associated with the production of 1 tonne of . The data were provided by Kisuma

Substances	Unit	Values
Water	m^3/t sorbent	46
	t/t sorbent	1.3
	t/t sorbent	0.9[1]

[1] *Total CO_2 emission: the value includes the emission due to the production of the sorbent (chemical reaction) and to the combustion of the natural gas.*

As the end sensor card is to be used in Europe, a European waste scenario has been assumed for end-of-life processing. The Netherlands has been chosen as a reference country because Ecoinvent has data for the Netherlands.

The study limitations are considered to be as follows:

- Due to the inherent limitations of LCA methodology, this study should not be used as the sole source of environmental information on the materials and processes modelled. There may be other environmental issues outside the remit of LCA. This LCA has been performed according to best practices in modelling and allocation.
- Due to the limitation of some substances that were not available within the Ecoinvent database, these were created based on composition information and desktop research.
- Intertek has not independently tested or verified that the stated quantities of alternative substances are in reality an accurate functional equivalent to the stated amount of Lead.

Results

Results are as follows:

ReCiPe impact assessment LCA results for the additives per kilogram of sensor card polymer

(ReCiPe is often considered to be the leading LCA method and reports a general range of environmental impacts):

Impact category	Unit	Lead				Lead Alternative
Global warming	kg CO2 eq	0.00197858	0.00683939	0.00272654	0.16618616	0.17575209
Stratospheric ozone depletion	kg CFC11 eq	0.00000000	0.00000000	0.00000000	0.00000005	0.00000006
Ionizing radiation	kBq Co-60 eq	0.00001000	0.00003287	0.00000361	0.00060883	0.00064531
Ozone formation, Human health	kg NOx eq	0.00000533	0.00001141	0.00000317	0.00038395	0.00039854
Fine particulate matter formation	kg PM2.5 eq	0.00000866	0.00000865	0.00000179	0.00056065	0.00057109
Ozone formation, Terrestrial ecosystems	kg NOx eq	0.00000540	0.00001196	0.00000321	0.00040807	0.00042323
Terrestrial acidification	kg SO2 eq	0.00002521	0.00001621	0.00000310	0.00052652	0.00054583
Freshwater eutrophication	kg P eq	0.00000014	0.00000020	0.00000002	0.00000845	0.00000867
Marine eutrophication	kg N eq	0.00000009	0.00000006	0.00000005	0.00000127	0.00000138
Terrestrial ecotoxicity	kg 1,4-DCB	0.07431962	0.01172331	0.00159777	0.32056410	0.33388518
Freshwater ecotoxicity	kg 1,4-DCB	0.00006469	0.00001536	0.00016374	0.00013129	0.00031039
Marine ecotoxicity	kg 1,4-DCB	0.00011738	0.00002008	0.00022612	0.00036636	0.00061255
Human carcinogenic toxicity	kg 1,4-DCB	0.00047797	0.00003705	0.00024619	0.00211425	0.00239749
Human non-carcinogenic toxicity	kg 1,4-DCB	0.02921918	0.00106948	0.00789897	0.03820279	0.04717124
Land use	m2a crop eq	0.00009605	0.00007798	0.00001252	0.00287386	0.00296437
Mineral resource scarcity	kg Cu eq	0.00259060	0.00001134	0.00000111	0.00083417	0.00084662
Fossil resource scarcity	kg oil eq	0.00035667	0.00218414	0.00011742	0.04221448	0.04451604
Water consumption	m3	0.00003176	0.00009681	0.00000470	0.00111240	0.00121392

USEtox impact assessment LCA results for additives per kilogram of sensor cards (USEtox focuses on human health):

Impact category	Unit	Lead				Lead Alternative
Human toxicity, cancer	nanocases	0.00074708314000	0.00023138130000	0.00002358611700	0.00662909740000	0.00688406480000
Human toxicity, non-cancer	nanocases	0.00011593662000	0.00021377652000	0.00006197931500	0.00618442650000	0.00646018230000
Freshwater ecotoxicity	PAF.m3.day	0.00000177536400	0.00158652530000	0.00000052235778	0.00037292249000	0.00195997020000

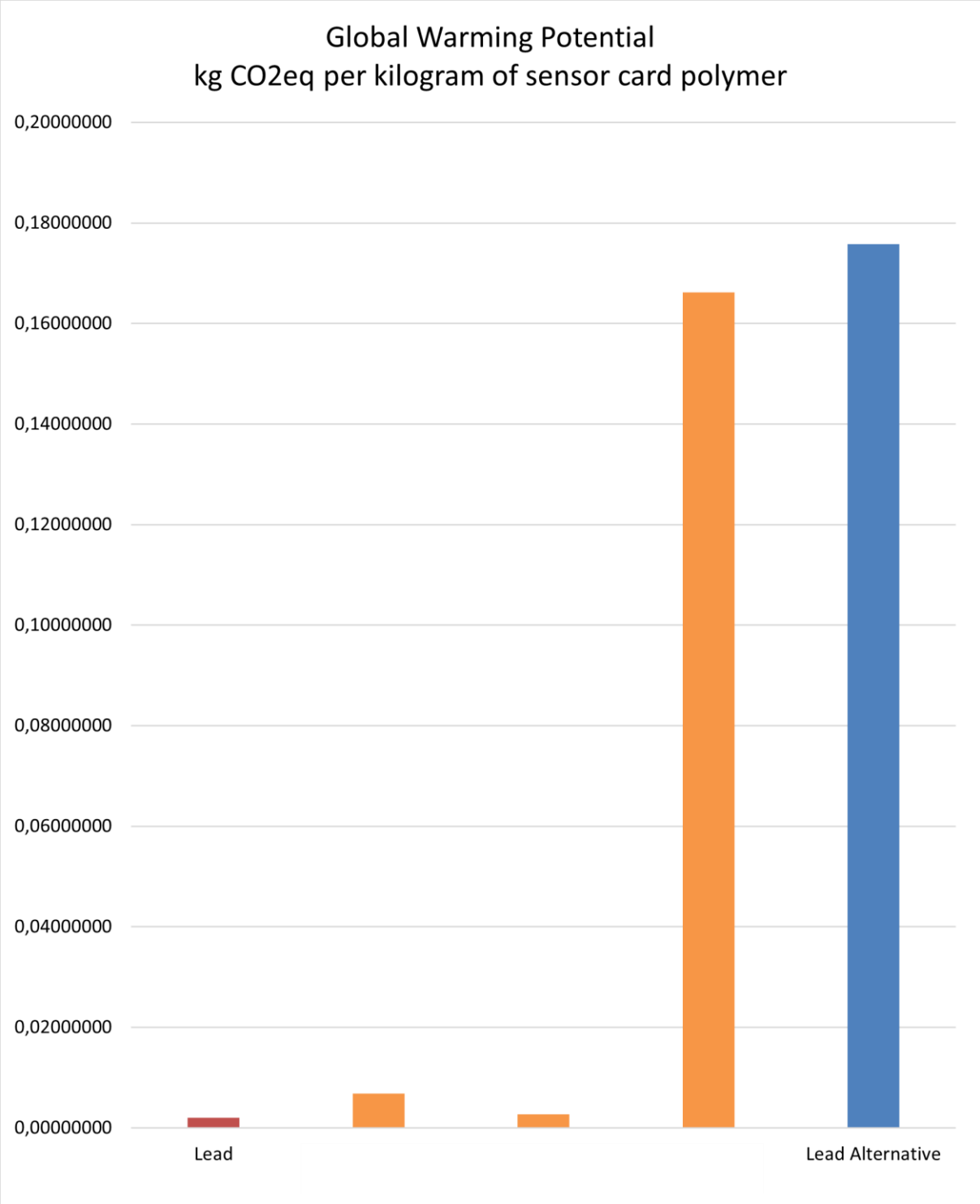
CED impact assessment LCA results for additives per kilogram of sensor cards (CED, Cumulative Energy Demand, focuses on energy):

Impact category	Unit	Lead				Lead Alternative
Non renewable, fossil	kJ	16.3419860	99.9756490	5.3873651	1943.8314000	2049.1945000
Non-renewable, nuclear	kJ	1.7690417	6.7167524	0.6140579	119.2530900	126.5839000
Non-renewable, biomass	kJ	0.0002697	0.0010540	0.0002149	0.0254302	0.0266992
Renewable, biomass	kJ	0.5479755	1.0755892	0.1161809	31.3917210	32.5834910
Renewable, wind, solar, geothe	kJ	0.2399876	0.7155621	0.0745847	16.0778290	16.8679760
Renewable, water	kJ	0.9763671	2.6367518	0.2650865	60.9624230	63.8642610

Ecopoint impact assessment LCA results for additives per kilogram of sensor cards (the Impact 2002+ method provides Ecopoints, a single-number result representing total environmental impact):

Damage category	Unit	Lead				Lead Alternative
Total	µPt	1.7700415	2.1880258	0.67521183	84.927324	87.790562
Human health	µPt	1.2865733	0.76006409	0.33263012	52.330052	53.422747
Ecosystem quality	µPt	0.1655146	0.096214521	0.037442378	4.0870836	4.2207405
Climate change	µPt	0.18537083	0.62905156	0.26561348	14.872242	15.766907
Resources	µPt	0.13258283	0.70269562	0.039525849	13.637947	14.380168

The following graph shows a summary of the global warming potential or carbon footprint for the additives modelled in the LCA study (per kilogram of sensor card polymer):



Carbon footprint results for additives Lead, _, plus the total of the three potential alternative additives, per kilogram of sensor cards

Interpretation

- The LCA for Lead showed a global warming potential or 'carbon footprint' of 0.00198 kgCO2eq, _ of 0.00684 kgCO2eq, _ of 0.00273 kgCO2eq and _ of 0.166 kgCO2eq (per kilogram of sensor card polymer).
- The alternatives to Lead are required in combination, so the true comparison is Lead with a carbon footprint of 0.00198 kgCO2eq versus the combined alternative additives with a carbon footprint of 0.176 kgCO2eq.
- The USEtox LCA results in the 'Human Toxicity, Cancer' category were 0.00075 nanoCases for Lead versus 0.00688 nanoCases for the combination of the other three additives.
- The USEtox results in the 'Human Toxicity, Non-Cancer' category were 0.000116 nanoCases for Lead versus 0.00646 nanoCases for the combination of the other additives.
- The results for Cumulative Energy Demand (CED) were lower in all cases for Lead than for the combination of the other additives; for example, in the 'Non-Renewable, Fossil' category, the result for Lead was 16.34 Kilojoules, while the result for the combination of the other additives was 2,049.19 Kilojoules.
- The Ecopoint method results showed that Lead achieved a score of 1.77 µPt versus 87.79 µPt for the combination of the other additives.
- These results are per kilogram of sensor card polymer. There are 196 sensor cards in a kilogram of sensor card polymer, so if it is ever required to consider the results per single sensor card, the results can be divided by 196.

Conclusion

The overall conclusion is that the LCA provides evidence that Lead has lower environmental impact (in terms of the measures produced by LCA) than the combined alternatives. The alternative additives when considered individually are within the same order of magnitude, except _. _ is a relatively unusual and high-impact substance. Also, 8 grams of _ are required per kilogram of sensor cards, which is significantly more than the 0.98 grams of Lead required. The combination of _ and other substances necessary to achieve the functional performance of Lead weigh a total of 11.2 grams per kilogram of sensor cards, versus Lead at 0.98 grams. The alternative combination has a potential environmental and health impact significantly higher than that of Lead, in terms of the measures produced by LCA. Lead faces other societal concerns that are outside the scope of LCA, but in terms of LCA metrics alone, Lead has lower (i.e. preferable) impacts.

References

[1] ISO, "ISO 14044:2006/AMD 1:2017 , Environmental Management - LCA - Requirements and guidelines - Amendment 1," ISO, 1 December 2017. [Online]. Available: https://www.iso.org/standard/72357.html.

[2] B. e. a. Weidema, "Overview and Methodology: Data Quality Guidelines for the Ecoinvent Database version 3," Ecoinvent Centre, St. Gallen, 2013.

[3] L. Rigamonti and E. Brivio, "From Residual steel gases to methanol - Preliminary Life Cycle Inventory (LCI) report on proposed methanol synthesis," February 2019. [Online]. Available: https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c1dbb17a&appId=PPGMS.

[4] International Standards Organization (ISO), *Environmental management - Life Cycle Assessment - Requirements and guidelines,* Geneva: International Standards Organization (ISO), 2006.

[5] European Commission - Joint Research Centre - Institute for Environment and Sustainability, "International Reference Life Cycle Data System (ILCD) Handbook - General Guide for Life Cycle Assessment," Publiciations Office of the European Union, Luxembourg, 2010.

[6] P. Sustainability, "Simapro," Pre Sustainability, [Online]. Available: https://simapro.com/.

[7] RIVM, Radbound Nijmegan, Leiden University and Pre Sustainability, "ReCiPe Midpoint Method," 2017. [Online]. Available: (http://www.rivm.nl/en/Topics/L/Life_Cycle_Assessment_LCA/Downloads/Documents_ReCiPe2017/Report_ReCiPe_Update_2017). [Accessed February 2020].

[8] International Standards Organization (ISO), *ISO 14040 Environmental management - Life Cycle Assessment - Principles and Framework,* Geneva: International Standards Organization (ISO), 2006.

[9] US EPA, "Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI) version 2.1, User Guide," Office of Research Development 600/R-12/554, Cincinnati, Ohio, 2012.

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?

Lead is a constituent material in the polyvinyl chloride (PVC) sensor card of the disposable cartridge used with the GEM Premier ChemSTAT analyzer.

The GEM Premier ChemSTAT enables rapid risk stratification and prioritization of acutely ill patients in the Emergency department. Expedited time to treatment for critically ill patients such as COVID-19 patients is essential for improving patient outcomes. Data from the GEM Premier ChemSTAT critical care analyzer is used regularly in hospitals around the world to make life-saving decisions regarding patient health. It is imperative that the data has the highest possible reliability and accuracy.

The sensor card is a vital component in the GEM Premier ChemSTAT cartridges as it contains the electrochemical sensors used for measuring and reporting concentrations of critical care analytes in blood (pH, *p*CO2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, haematocrit, creatinine, blood urea nitrogen and tCO_2). Any change in the sensor card resin can directly impact analytical performance characteristics and thereby impede the intended function of the GEM Premier ChemSTAT analyzer.

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

PVC has specific advantages as a sensor card material for the electrochemical sensors used in the GEM Premier ChemSTAT. Sensor membranes used for certain sensors (Creatinine, Blood Urea Nitrogen, Glucose, Lactate, Na^+, K^+, Ca^{++}, pH, *p*CO2) are based on polymer membranes and are solvent cast directly on the sensor card from a solution of tetrahydrofuran (THF) and cyclohexanone (CHO). Because THF/ CHO is a strong solvent for PVC card, there is strong adhesion between the cast membranes and the PVC card. This membrane adhesion to the PVC is a critical requirement for sensor function and claimed use life and shelf life.

Any change to the sensor card resin can directly impact analytical performance characteristics of the GEM Premier ChemSTAT. Any change to sensor materials is especially critical for Creatinine and Blood Urea Nitrogen sensors. These new sensors are the most complicated sensors we manufacture. Creatinine is a two-sensor system consisting of 3 enzyme populations held under a delicate and thin (only ~3 um thick) polymer membranes. The BUN sensor contains 4 distinct polymer and enzyme layers. Any change to sensor card material or composition may impact analytical performance of either of these sensors.

Additionally, any change in the sensor card resin can impact the raw sensor results to inform the GEM Premier ChemSTAT intelligent Quality Management System (iQM™), which ensures high quality and accurate blood measurements. The following advantages of the GEM Premier ChemSTAT as compared to other existing

technologies on the market today are directly related to resin formulation and require extensive validation for an alternative substance:

1. The GEM Premier ChemSTAT analyzer utilizes the renowned Intelligent Quality Management (iQM™). iQM is an active quality management program designed to provide continuous monitoring of the analytical processes before and after sample measurement in real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, thus replacing the use of traditional external quality controls, iQM performs continuous quality checks to monitor the performance of the cartridge, sensors, and reagents throughout the cartridge use life.
2. The GEM Premier ChemSTAT analyzer offers a single, disposable measurement cartridge which can be stored up to 5 months at room temperature. Other competing technologies utilize multiple cartridges to perform the same functions, some of which require refrigerated storage. This places an additional burden on the customer to stock multiple consumable cartridges and providing refrigerated storage at point-of-care testing locations, where space is often limited. Any change in the sensor card resin can impact the shelf life, which will be tested in the validation phase.
3. Every sensor card produced for the GEM Premier ChemSTAT analyzer is 100% QC tested to ensure highest levels of quality to the customer.

The combination of the iQM technology, single measurement cartridge design, and rigorous testing procedure for each sensor card ensures that the GEM Premier ChemSTAT analyzer provides the best possible results in all relevant use scenarios. The GEM Premier ChemSTAT minimizes the need for external corrective actions, thereby enabling the healthcare staff to better focus on critical patient care tasks. These advantages are directly linked to the performance of the sensor card resin as a critical component of the measurement system.

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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.)

The GEM Premier ChemSTAT cartridge is treated as medical waste, and its disposal is handled in each country per their local, state, and federal laws. In most cases, medical waste is incinerated in specific designated facilities according to national requirements and supervision of the respective EU Member States.

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: _____
X Article cannot be recycled and is therefore:
    X 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 _____
X In articles which are sent for energy return 0,5-10 kg
☐ In articles which are landfilled _____

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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

Instrumentation Laboratory has carried out an extensive RoHS compliance program to ensure compliance for equipment falling under the scope of RoHS and supplied to the EU by Instrumentation Laboratory. Please also refer to Point 4(A)(6) and Appendix F regarding the environmental assessment.

The compliance program identified the sensor card of the GEM Premier ChemSTAT analyzer as a component with a content of lead exceeding the maximum concentration value of 0.1% as defined in Annex II of RoHS directive. Lead is present in the PVC resin of the sensor card to act as a thermal stabilizer and prevent breakdown of the PVC resin during high temperature injection molding process required to produce the sensor card.

Currently, Instrumentation Laboratory has been actively working to replace lead as a thermal stabilizer in the GEM Premier ChemSTAT PVC sensor card. Based on feasibility performance, RoHS CMR 1345 has been identified as the primary candidate. The same resin has been verified on other GEM platforms. Analytical feasibility testing summary is shown in Appendix B. The next steps are analytical verification, release

documentation and controlled distribution of GEM Premier ChemSTAT cartridges with RoHS CMR 1345 resin sensor card. A

Instrumentation Laboratory is submitting this application for an exemption to allow additional time to complete this work while at the same time assuring uninterrupted supply to the EU healthcare sector of equipment critical to providing optimum care of critically ill patients.

Based on our evaluations we conclude that this application for an exemption falls within all three categories as established in Article 5(1)(a) with respect to the possibility to substitute the use of lead as a thermal stabilizer in the PVC material of the sensor card:

1. Their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable,
2. The reliability of the substances investigated for substitution is not ensured.
3. The total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.

Due to the additional complexity of Creatinine and Blood Urea Nitrogen sensors on the GEM Premier ChemSTAT , more diligence is required to convert to a RoHS resin than the other GEM Premier platforms. Due to slight differences in cartridge, electromechanical, and system designs, together with unique interactions with the sensor cards resin, removal of lead was shown to impact analytical performance characteristics. Based on feasibility studies, RoHS CMR 1345 shows acceptable analytical performance on all sensors. The next step requires verification effort for GEM Premier ChemSTAT to ensure the consistency of manufacturing, accuracy of results, and patient safety and effectiveness.

As noted above under Point 4(A)(6) the results of the LCA shows that the current GEM Premier ChemSTAT sensor card has a lower environmental impact than the potential alternative Sensor Card.

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

Please see Appendix B: Testing Summary of GEM Premier ChemSTAT with Sensor Card Resin Compliant with Directive 2011/65/EU. Feasibility testing was performed on GEM Premier ChemSTAT using RoHS compliant ColorMaster (CMR) Resin 1345. Analytical testing on over sixty (60) cartridges using nine (9) RoHS CMR 1345 card lots was performed for new sensors specific to GEM Premier ChemSTAT. The testing was focused on the unique sensors – Creatinine and BUN. Based on the feasibility testing, RoHS CMR 1345 resin has met analytical requirements for accuracy, precision and

use life stability, and is considered the primary resin candidate for verification tests. The analytical verification will also include shelf life testing of RoHS cartridges at >5 months in order to show continued compliance with our current 5 month cartridge shelf life specification.

With the completion of feasibility using RoHS CMR 1345, there is high confidence in the RoHS sensor card resin analytical performance and timeline to complete next steps. The extensive verification testing required by our Design Control procedures will ensure analytical performance meets all specifications, and patient safety and effectiveness. This is necessary to maintain compliance with Directive 98/79/EC, cf. Article 3 and Annex 1. This is the focus of the Project Plan as shown in Appendix C. We are confident that the successful replacement of sensor card resin on the GEM Premier ChemSTAT will be concluded by Q4 2023, as shown in Appendix D.

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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.

Actions to develop alternative substances are currently in progress. Table 1 shows milestones listed in the project schedule submitted as part of Appendix D. Also, included in the table is the progress (% Complete column) made towards each milestone.

Table 1: Project Plan

Task Name	Notes	% Complete
Design and Process Optimization	Dec 2017	100%
Down select top 3 formulations from CMR additional additives	Jan 2018	100%
Analytical Performance testing, partial shelf life stability up to 3 Months	Feb 2018	100%
Testing on all GEM platforms for top 3 candidates from CMR additional additives	Apr-May 2018	100%
Repeat testing on all GEM platforms for top 3 candidates	Aug-Sep 2018	100%
Design Review	Oct 2018	100%

Material properties testing	Aug 2018	100%
Down select top 2 resins	Oct 2018	100%
Feasibility	2019	100%
1345 and 1346 Feasibility	Jan 2019	100%
1345 + 1346 Method Comparison and Precision Testing	Apr – May 2019	100%
Additional 1345 + 1346 MC and Prec. Testing	Sep – Oct 2019	100%
1345 Creatinine Investigation	Nov 2019	100%
1345 + 1348 MC and Prec. Testing	Jan 2020	100%
1345 Creatinine interference testing	Mar 2020	100%
1345 Shelf Life Testing	Jun-Oct 2020	100%
1345 Use Life Testing	Jul 2020	100%
Creatinine CVP Optimization	Aug – Nov 2020	100%
Feasibility Review	Jan 2021	100%
Performance Testing to exit Feasibility	Jan - Jun 2021	100%
Process Validation - Sensor Card Molding*		90%
Molding Validations on all platforms	Q1-Q4 2019	100%
Risk Assessment for drying resin	Feb 2020	100%
ChemSTAT molding validation IQ/OQ	Aug 2020	100%
PQ Validation (SMC)	Aug 2020	100%
Pin Cards	Dec 2020	100%
Manufacturing Validation	Mar-May 2021	100%
PQ Validation Report	Q4 2021	0%
Analytical Verification – 1*		25%
Build Material for Verification	Mar-Sep 2021	30%
Analytical Verification	Apr-Sep 2021	10%
Method Comparison	Q4 2021	0%
Aqueous Precision	Q4 2021	0%
Use Life	Q4 2021	0%
Systems Verification	Q4 2021	0%
Shelf Life Verification	Apr-Dec 2021	50%
ELM Testing	Q3 2021	100%
Verification Reports for Analytical Verification – 1	Q1 2022	0%

Testing ~500 Clinical Samples over 10 RoHS CMR1345 resin lots	Q1-Q2 2022	0%
Analytical Verification – 2 (contingency)		0%
Build Material for Verification	Q2-Q3 2022	0%
Analytical Verification	Q3-Q4 2022	0%
Method Comparison	Q3 2022	0%
Aqueous Precision	Q3 2022	0%
Use Life	Q3 2022	0%
Systems Verification	Q4 2022	0%
Shelf Life Verification	Q3 2022 – Q1 2023	0%
Verification Reports for Analytical Verification – 2	Q2 2023	0%
Release Documentation	Q3 2023	0%
Controlled Distribution of RoHS Resin	Q3-Q4 2023	0%

*Delay due to increased demand to support COVID-19

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

Please see Appendix C and Appendix D: RoHS Compliance of the GEM Premier ChemSTAT Sensor Card Resin Project Plan and GEM ChemSTAT RoHS Project Schedule respectively.

Table 1 above shows milestones for executing project plan. Please note that we plan to complete the project between Q3 and Q4 2023.

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
- ☐ Registry of intentions

☐ Registration

2) Provide REACH-relevant information received through the supply chain.
Name of document: No information specific for REACH received

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?
   - ☐ Yes. Consequences? _____
   - ☒ No. Justification: Alternatives are currently not available
2. Can the substance named under 4.(A)1 be substituted?
   - ☐ Yes.
     - ☐ Design changes:
     - ☐ Other materials:
     - ☐ Other substance:
   - ☒ No.

     Justification: Alternatives are currently not available
3. Give details on the reliability of substitutes (technical data + information): Alternatives are currently not available
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: Please refer to point 4(A)(6) and Appendix F.
   2) Health impacts: Please refer to point 4(A)(6) and Appendix F
   3) Consumer safety impacts: EEE is only sold to professionals

⇨ Do impacts of substitution outweigh benefits thereof?
Please provide third-party verified assessment on this: Please refer to point 4(A)(6) and Appendix F.

(C) Availability of substitutes:

a) Describe supply sources for substitutes: Alternatives are currently not available

b) Have you encountered problems with the availability? Describe: Alternatives are currently not available

c) Do you consider the price of the substitute to be a problem for the availability?

☐ Yes X No

d) What conditions need to be fulfilled to ensure the availability? Alternative must not impede the reliability of test results carried out with the sensor card as the alternative must ensure that the analyzer performs its intended function within established product claims

(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

X Other: Alternatives are currently not available

⇨ Provide sufficient evidence (third-party verified) to support your statement: Not relevant as alternatives are currently not available.

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:
