Exemption Request Form

Date of submission: 01.08.2025

1. Name and contact details

1) Name and contact details of applicant:

Company: BANDELIN electronic GmbH & Co. KG	Tel.: +49 30 768800
Name: Dipl.-Ing. Stefan Bandelin	E-Mail: Stefan.bandelin@bandelin.com
Function: Managing Partner	Address: Heinrichstr. 3 – 4 12207 Berlin Germany

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

Company:	-/-	Tel.:	-/-
Name:	-/-	E-Mail:	-/-
Function:	-/-	Address:	-/-

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2. Reason for application:

As a manufacturer of high-performance ultrasonic devices for cleaning and process technology, we are applying for an extension of the exemption.

We have been using HPZT rings or discs as ultrasonic transducers in various devices for more than 65 years. We work with frequencies between 20 kHz and 55 kHz. Our company currently employs 110 people. Additional employees work for our suppliers, who manufacture various components according to our specifications that we are unable to produce ourselves. As we only manufacture high-performance ultrasonic devices and accessories, all of these jobs are at serious risk.
You can find our range of various devices at http://www.bandelin.com. Our devices are used in medicine, laboratories, industry and service.

Our four largest competitors are also SMEs with roughly the same number of employees and similar structures. Jobs are also at risk there.

Furthermore, many plant manufacturers who are customers of high-performance ultrasonic technology depend on its use in automated systems.

High-performance ultrasound is a precision cleaning process and is used, for example, as a final cleaning step in industrial manufacturing after spray cleaning, which removes coarse dirt.
In addition, high-performance ultrasonic cleaning is a very environmentally friendly cleaning method that saves up to 90% of the surfactants required for a cleaning task, thus significantly reducing the impact on the environment.
In the field of instrument reprocessing for robotic instruments from INTUITIVE (https://www.intuitive.com/en-gb), their instruments cannot be adequately cleaned in the cleaning and disinfection device (RDG). If our TRISON device (https://bandelin.com/produkte/medizin/trison) is used before the RDG, the protein load is reduced to the value that is actually required as the limit value for residual contamination after the RDG by means of alternating rinsing and ultrasound.

In process engineering, the use of high-performance ultrasound enables energy-intensive processes, for example, by eliminating the need for temperature control at ambient temperature. Biological processes are also positively supported, which leads to less environmentally harmful sewage sludge in sewage treatment plants, for example.

All the positive effects of high-performance ultrasound are jeopardised if there are no longer any exceptions.

Please indicate where relevant:

- ☐ Request for new exemption in:
- ☐ Request for amendment of existing exemption in
- ☒ Request for extension of existing exemption in
- ☐ Request for deletion of existing exemption in:
- ☒ Provision of information referring to an existing specific exemption in:
  - ☐ Annex III ☒ Annex IV

No. of exemption in Annex III or IV where applicable: Exemption 14, Annex IV

Proposed or existing wording: Lead in piezoelectric single crystals for ultrasonic transducers

Duration where applicable: 7 years

- ☐ Other:

3. Summary of the exemption request / revocation request

We request that the exemption continue to apply.

We request that the exemption be extended for as long as possible within the framework of the applicable guidelines.

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4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products:

High-performance ultrasonic baths
High-power ultrasonic cleaning devices
High-performance ultrasonic homogenisers
High-power ultrasonic reactors

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

☐ 1	☐ 7
☐ 2	☒ 8
☐ 3	☐ 9
☐ 4	☐ 10
☐ 5	☒ 11
☐ 6	

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

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: Reliable generation of ultrasonic vibrations in ultrasonic transducers

4. Content of substance in homogeneous material (%weight): The lead content is approximately 60%.

5. Amount of substance entering the EU market annually through application for which the exemption is requested: unknown. We have several competitors in Germany whose quantities we do not know. The delivery quantity could be requested from the manufacturer of the HPZT, CERAMTEC (https://www.ceramtec-group.com/en). We do not have this information. For us, this means: 34,942 pieces in 12 months x 49.3 g x 60% = 1,034 kg. Our data comes from our ERP system and from weighing the part.
   Please supply information and calculations to support stated figure.

a. Name of material/component:
   SONOX P 4
   SONOX P 8

6. 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 PZT material is used in the form of a ring in high-performance ultrasonic transducers.
The material converts electrical power into mechanical motion, thereby making a significant contribution to the generation of high-performance ultrasound.

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

Its excellent efficiency and high temperature stability.

The efficiency can be determined by the loss factor tan δ, which is a maximum of 3 for lead-containing materials and above 5 for lead-free materials.
This results in more losses than heat in the material, which contributes to its

temperature increase.

The limit value for temperature stability is half the Curie temperature. If this value is exceeded, the material loses its piezoelectric properties. Due to self-heating of the material during use, the application temperature is often very high, for example with boiling liquids in an ultrasonic bath.

These examples illustrate why it is currently impossible to replace lead-containing HPZT ( ) with lead-free HPZT.

For further information, please refer to the data sheets:

Data sheet for lead-containing HPZT piezo ceramics

Materialeigenschaften

Werkstoff			Sonox® P4	PZT401	PZT406	Sonox® P8	PZT807
Navy Type			I	I	II	III	III
Dielektrische Eigenschaften							
Relative Dielektrizitätszahl ε_r	$\varepsilon_{33}{}^{T}/\varepsilon_0$ $\varepsilon_{33}{}^{S}/\varepsilon_0$ $\varepsilon_{11}{}^{T}/\varepsilon_0$ $\varepsilon_{11}{}^{S}/\varepsilon_0$		1300 660 1535 885	1395 735 1330 680	1325 660 1295 980	1000 540 1250 800	1105 625 1190 830
Verlustfaktor tan δ		10^{-3}	3,0	2,0	1,8	2,0	1,6
Curietemperatur T_c		C°	325	330	325	305	300
Elektromechanische Eigenschaften							
Frequenzkonstante	N_p N_t N_1 N_3	KHz x mm	2210 2000 1480 1340	2190 2080 1635 1550	2190 2015 1530 1500	2280 2020 1600 1490	2320 2030 1720 1660
Kopplungsfaktor	k_p k_{31} k_{33} k_t k_{15}		0,57 0,31 0,68 0,50 0,65	0,58 0,35 0,67 0,50 0,70	0,61 0,34 0,70 0,47 0,60	0,55 0,30 0,68 0,48 0,60	0,55 0,29 0,69 0,47 0,58
Ladungskonstante	d_{33} d_{31} d_{15}	10^{-12} C/N	310 -130 455	315 -130 510	315 -130 550	240 -95 380	260 -90 295
Spannungskonstante g_{33}		10^{-3} Vm/N	26,9	25,5	26,9	27,1	26,6
Mechanische Eigenschaften							
Elastische Nachgiebigkeit	$S_{11}{}^{E}$ $S_{11}{}^{D}$	10^{-12} m²/N	14,9 18,1	12,7 15,6	13,0 15,0	11,4 13,7	10,9 15,7
Elastische Steifigkeit	$C_{11}{}^{E}$ $C_{55}{}^{D}$	10^{10} m²/N	15,9 4,8	15,0 4,9	15,2 4,0	16,2 4,5	16,3 4,7
Dichte ρ		10^3 kg/m²	7,65	7,60	7,80	7,70	7,60
Gütefaktor Q_m			500	600	750	1000	1200
Stabilität							
Alterungsrate	Kapazität Frequenz Kopplungsfaktor	%/Dekade	-4,5 1,0 -1,6	-4,6 1,0 -1,5	-6,0 0,5 -2,5	-3,0 0,8 -2,0	-3,5 0,8 -1,5

Die hier aufgeführten Werkstoffparameter wurden an Prüfkörpern ermittelt und sind als Richtwerte anzusehen. Die Werte wurden auf der Grundlage von nationalen und internationalen Normen bestimmt. Falls solche Normen nicht vorhanden waren, wurden die Parameter anhand CeramTec interner Meßvorschriften bestimmt. Die hier angegebenen Werkstoffeigenschaften stellen keine Garantie für bestimmte Produkteigenschaften von piezoelektrischen Bauelementen dar. CeramTec und ihre Tochtergesellschaften übernehmen keine Verantwortung für die Richtigkeit dieser Informationen oder für aus der Nutzung dieser Informationen resultierende Schäden. Bitte beachten Sie, dass Werkstoffspezifikationen bzw. die hier angegebenen Informationen jederzeit geändert werden können."

CeramTec

Data sheet for lead-free HPZT piezoceramics

provisional datasheet (Changes and deviations possible), status: 31.01.2023
standard tolerance range is ±20%

CeramTec
THE CERAMIC EXPERTS

Werkstoff Material			SONOX®LF1	SONOX®LF100	SONOX®LF160	SONOX®LF161
Dielektrische Eigenschaften Dielectric properties						
Relative Dielektrizitätszahl ε_r Relative permittivity ε_r	$\varepsilon_{33}^T/\varepsilon_0$		1150	489	709	504
	$\varepsilon_{33}^S/\varepsilon_0$		830	360	444	403
	$\varepsilon_{11}^T/\varepsilon_0$		1330	393	931	781
	$\varepsilon_{11}^S/\varepsilon_0$		1140	381	749	737
Verlustfaktor tan δ Dielectric dissip. factor tan δ		10^{-3}	8	30	21	5
Depolarisationstemperatur T_d Depolarisation temperature T_d		°C		163	110	140
Elektromagnetische Eigenschaften Electromechanical properties						
Frequenzkonstante Frequency constant	N_p	kHz*mm	3180	2962	3000	3089
	N_t	kHz*mm	2640	2422	2257	2257
	N_1	kHz*mm	2300	2367	2269	2317
	N_3	kHz*mm	2330	2237	2093	2138
Kopplungsfaktor Coupling coefficient	k_p		0,31	0,15	0,30	0,19
	k_{31}		0,18	0,11	0,19	0,12
	k_{33}		0,43	0,39	0,50	0,48
	k_t		0,45	0,44	0,51	0,50
	k_{15}		0,38	0,17	0,44	0,24
Ladungskonstante Charge constant	d_{33}	10^{-12} C/N	135	83	172	129
	d_{31}	10^{-12} C/N	-52	-20	-45	-18
	d_{15}	10^{-12} C/N	210	43	183	91
Spannungskonstante g_{33} Voltage constant g_{33}		10^{-3} Vm/N	14	19,2	27,4	25,8
Mechanische Eigenschaften Mechanical properties						
Elastische Nachgiebigkeit Elastic compliance	s_{11}^E	10^{-12} m²/N	8,2	7,7	8,4	8,2
	s_{33}^E	10^{-12} m²/N	8,5	8,9	10,4	10,1
Elastische Steifigkeit Elastic stiffness	c_{33}^D	10^{10} N/m²	14,6	16,3	15,2	14,7
	c_{55}^D	10^{10} N/m²	36,5	5,7	6,0	5,0
Dichte ρ Density ρ	ρ	10^3 kg/m³	5,7	5,8	5,8	5,7
Gütefaktor $Q_m(k_p)$ Mechan. Quality factor Q_m (k_p)			310	240	140	738
Stabilität Stability						
Alterungsrate Aging rate	Capacitence	%/Dekade	-0,5	-0,5	9,5	6,9
	Frequency (k_t)	%/Dekade	0,1	0,1	2,1	-0,1
	Coupling (k_t)	%/Dekade		-0,3	-0,9	-1,1

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.)

Our high-performance ultrasonic devices are marked with the symbol  . They must be dismantled by specialist companies and recycled or disposed of in accordance with the law, depending on the material.

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: The manufacturer of the HPZT will take these back separately. We have no information about further processing.

☐ 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

☐ In articles which are sent for energy return

☐ 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

Various groups around the world are continuing to actively work on the topic of lead-free HPZT piezo materials. The statement made by the manufacturer CERAMTEC in its press release on the development of lead-free ceramics on 30 November 2020: "The big challenge is to achieve the properties of conventional lead-containing ceramics" remains unchanged.
Research into lead-free piezo ceramics was carried out and funded at the Technical University of Darmstadt: AZ: AL 578/23-1.
Project period: Funding since 2019, project start: 07.2021.
No results report is available for the project to date.

A project on lead-free piezo ceramics was carried out at the Albert Ludwig University of Freiburg from 1 July 2020 to 30 June 2023. The title, "LEAP Lead-free programmable multistable piezo-thermal actuators," does not relate to high-performance ultrasound.

The article ‘Environment-friendly technologies with lead-free piezoelectric materials: A review of recent developments, applications, and modelling approaches’ published on 27 February 2025 describes a large number of material variants [https://arxiv.org/abs/2502.20250]. However, these are only for small signal applications, for example such as in sensors or actuators. Our difficulties with HPZT materials cannot be deduced from this.

No articles were found for the material HPZT in power applications.

These are just a few examples and do not provide an exhaustive overview. All these efforts are an indication of the urgent need for basic research. The results must then be translated into marketable products and put into use.

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

No valid data is available.

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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.

These measures must be taken by the manufacturers of the HPZT, as we only use the finished product without developing it ourselves.

Since lead-free HPZT rings became available in the Far East, we have repeatedly obtained samples from there and carried out tests with our equipment. Unfortunately, these tests were very unfavourable in terms of the ultrasonic power required by the user. Even redesigns, where technically feasible, such as increasing the number of transducers under a high-performance ultrasonic cleaning tank, did not produce marketable results. Continued trials, including with high-performance ultrasonic homogenisers, unfortunately confirm this situation.

Recently, our supplier, CERAMTEC, has developed new lead-free HPZT materials. The data sheet for these materials is provided above, together with the data sheet for the lead-containing HPZT materials. The data already shows that the requirements in the field of high-performance ultrasound are not nearly met.

The production of lead-free ceramics is significantly more expensive. This also

suggests the generation of environmentally harmful waste materials or high energy consumption.

We are continuing our search for suitable lead-free HPZT materials, both in Germany and worldwide. We are also happy to continue supporting development through testing and the construction of test equipment as soon as further HPZT materials are available as samples.

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

The following parameters of lead-free HPZT piezo materials are unsuitable for use in high-performance ultrasonic technology:

Lead-free piezo materials have a significantly lower piezo coefficient. They require considerably more electrical power to generate the required ultrasonic power, i.e. a higher current consumption for the same cleaning performance. Due to the low piezo coefficient, the lead-free piezo material heats up much more during operation.

Lead-free piezo material has a lower Curie temperature. When the Curie temperature is reached, the piezo ceramic depolarises and becomes unusable as an oscillator. As described above, this is more likely to occur at high temperatures.

The electrical ultrasonic generators must be completely redesigned. This also means new circuit designs and intensive testing, even over several months. It is possible that completely different device designs will have to be developed due to the required forced ventilation, which would lead to a significant increase in costs due to the additional components and thus to higher procurement costs for users. These devices would then also have to be tested for several months.

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 documents are passed on.

(B) Elimination/substitution:

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

☐ Yes. Consequences?

☒ No. Justification: The high-performance ultrasound devices would no longer generate ultrasound.

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

☐ Yes.

☐ Design changes:
☐ Other materials:
☐ Other substance:

☒ No.

Justification: There is no suitable substance for this yet, as explained in the application, due to technical difficulties.

3. Give details on the reliability of substitutes (technical data + information): This information is not yet available as no long-term tests have been carried out to date because the substitute material is not available in sufficient quantities for these tests.
4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to
   1) Environmental impacts: We are unable to make this ecological statement.
   2) Health impacts: We are unable to make this medical statement.

3) Consumer safety impacts: There is no effect, as we only target commercial users.

⇨ Do impacts of substitution outweigh benefits thereof?

Please provide third-party verified assessment on this: This review cannot be provided yet.

(C) Availability of substitutes:

a) Describe supply sources for substitutes: The company CERAMTEC.

b) Have you encountered problems with the availability? Describe: Handcrafting does not produce sufficient quantities. In addition, the technical properties vary greatly and are therefore not suitable for series production.

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? The technical properties must be comparable without too large a price increase for the HPZT parts.

(D) Socio-economic impact of substitution:

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

☒ Increase in direct production costs

☐ Increase in fixed costs

☐ Increase in overhead

☐ Possible social impacts within the EU

☐ Possible social impacts external to the EU

☒ Other: Increase in the purchase price for our commercial users.

⇨ Provide sufficient evidence (third-party verified) to support your statement: As the costs of series production of the HPZT parts are not available, no evidence can be provided.

9. Other relevant information

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

None

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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:

None