REPUBLIC OF ESTONIA
HEALTH BOARD

EEDEROSurvey2023

Derogation from the conformity assessment procedure

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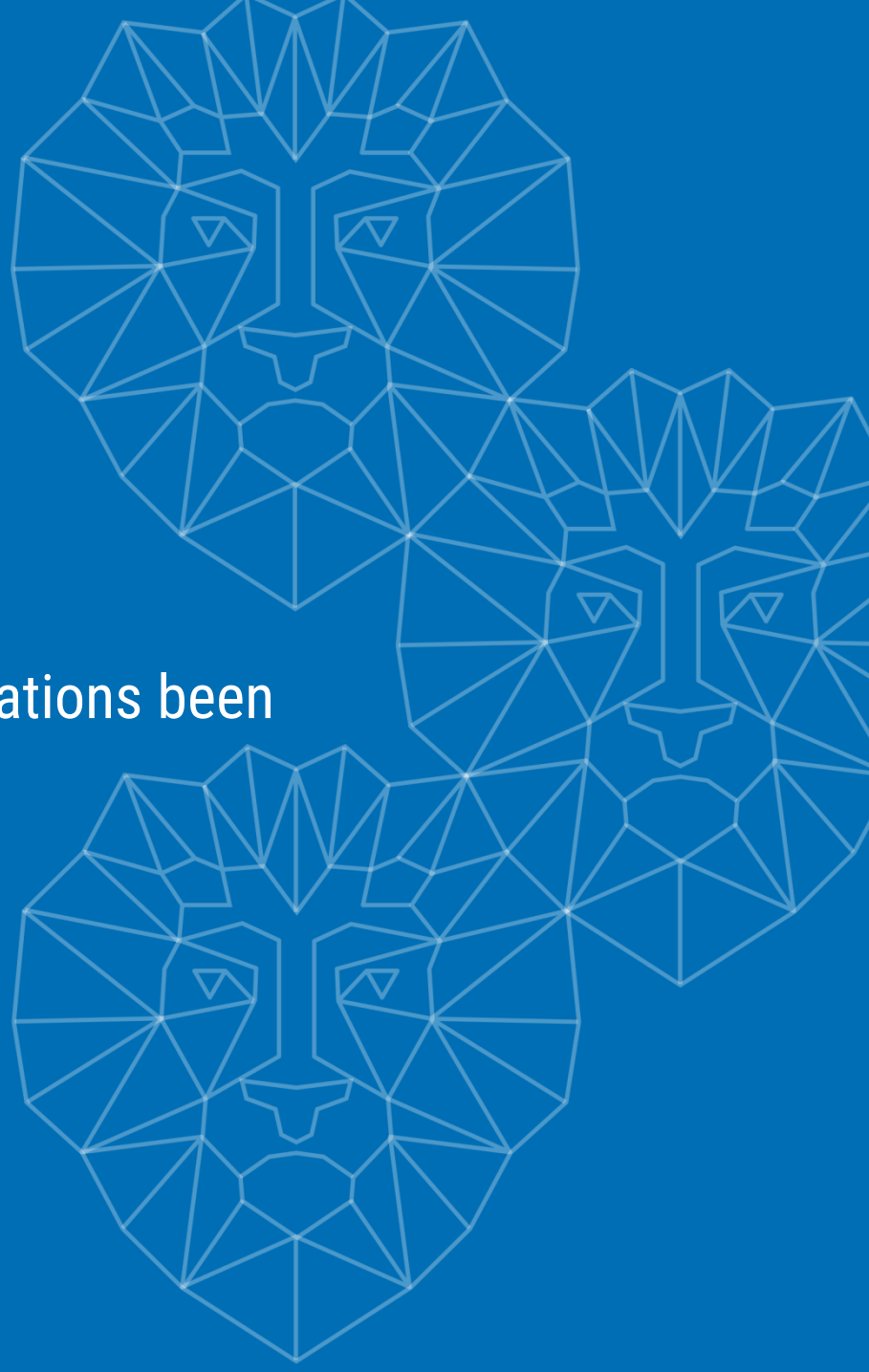
Background

Given the complexity of dealing with derogations from the conformity assessment procedure established with Article 59 of the MDR (EU) 2017/745 and Article 54 of the IVDR (EU) 2017/746, it was planned to carry out a study in order to establish procedures and develop application templates in Estonia.

AIM

1. How have the procedures for these two different derogations been established in other member states?

2. What are the countries' experiences in processing derogations?



Content

1. General information
   country, institution, general e-mail address of the entity(-ies) processing the derogation
2. National derogation
3. Compassionate use/single patient derogation
4. Further information
   experience, comments
5. Future plan regarding derogations

Results

19 countries participated

The survey lasted between 16.01-29.02.2024

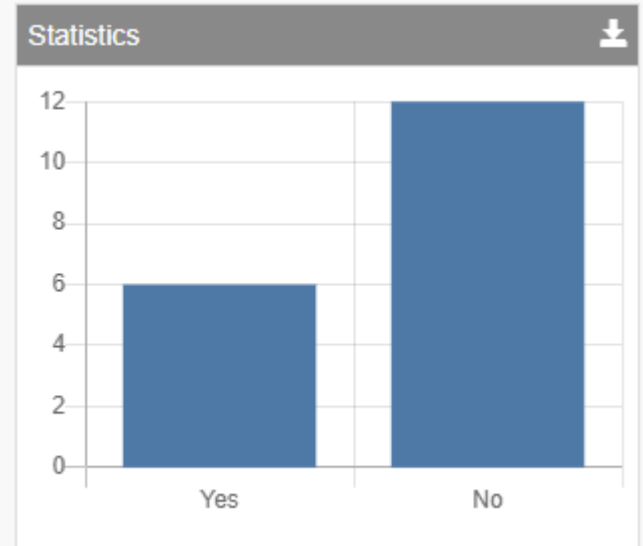
National derogation

MDR 2017/745 Article 59

IVDR 2017/746 Article 54

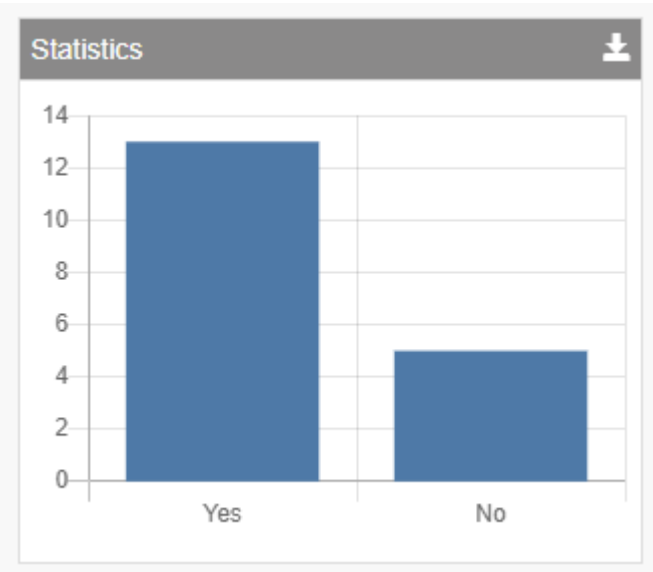
Is the procedure for making derogation laid down in national law?

		Answers	Ratio
Yes		6	31.58 %
No		12	63.16 %
No Answer		1	5.26 %



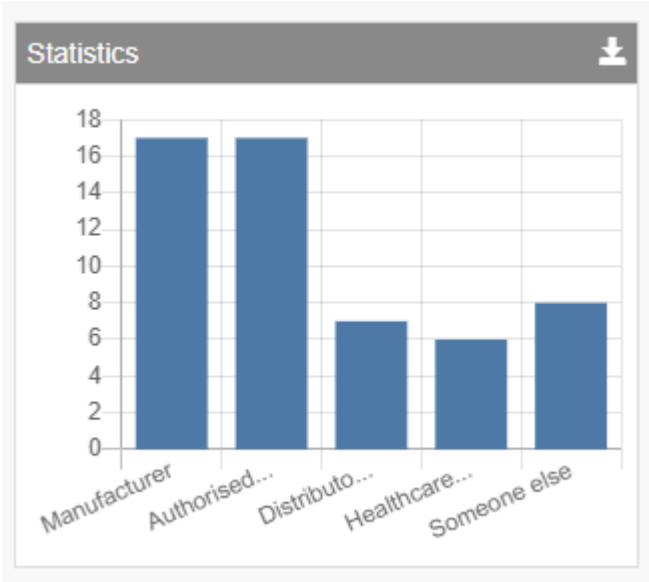
Do you have standard application/request templates?

		Answers	Ratio
Yes		13	68.42 %
No		5	26.32 %
No Answer		1	5.26 %



Who can apply for a derogation?

		Answers	Ratio
Manufacturer		17	89.47 %
Authorised representative		17	89.47 %
Distributor/importer		7	36.84 %
Healthcare institution/professional user		6	31.58 %
Someone else		8	42.11 %
No Answer		1	5.26 %



Someone else who can apply

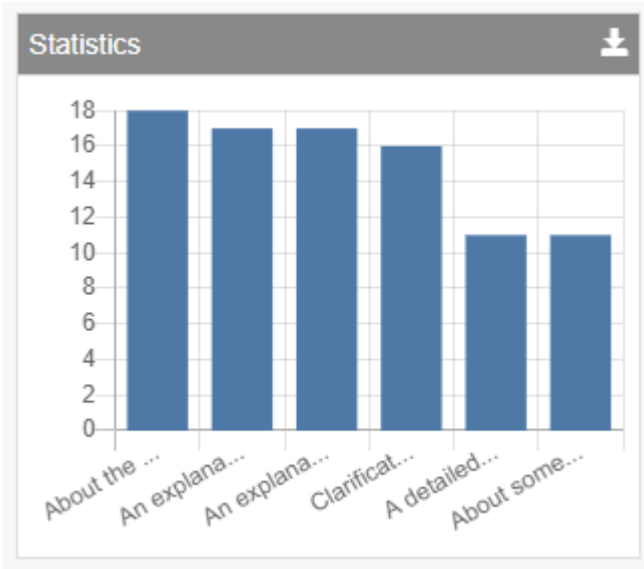
- Ministry of Defence may derogate from the Act on MDs but only as a distributor or service person
- Everybody can apply for an exceptional derogation but only the manufacturer or owner of the device can receive the approval
- Who wants is not determined
- Legally everybody, practically only with the cooperation of the manufacturer
- Dual application from manufacturer/authorized rep and healthcare professional needs to be submitted, the healthcare professional application should be completed by an appropriately senior clinician, who is a representative of the relevant health service being provided, e.g. at institutional or national level
- If other economic operators other than the manufacturer apply, they must submit the authorization certificate obtained from the manufacturers that they represent in order to apply for derogation
- All the other if authorized by the manufacturer
- The derogation is always granted to the manufacturer or its authorized representative, even if it is the distributor who initiates the request
- An application for an exemption authorization can be submitted by anyone who is responsible for placing the device on the market or putting it into service
- It is not determined by law who is allowed to apply for a derogation
- If it is not the manufacturer, we like to see a proxy, but we see the manufacturer as the one who can apply
- Any other person duly mandated by the manufacturer or its authorized representative (a contract signed by both parties must prove this mandate)

In summary: who can apply

- There is no provision on who can apply
- Derogation granted to the manufacturer or EU-REP
- The manufacturer must be linked to the derogation

When you ask about the reasons for the derogation, do you ask...

		Answers	Ratio
About the non-conformity(ies)		18	94.74 %
An explanation why the compliance assessment has not been started or completed		17	89.47 %
An explanation why the use of a medical device is vital		17	89.47 %
Clarification on the period for which the derogation is requested		16	84.21 %
A detailed plan on how to ensure compliance or withdrawal of the device from the market after the temporary derogation has expired		11	57.89 %
About something else		11	57.89 %
No Answer		1	5.26 %



Other reasons for derogation

- Suitable alternatives available
- Medical expertise, a statement of the NB, conformity to safety and performance requirements, approval or certification in other industrial states worldwide, experiences in human/animal studies, current completed or planed clinical trials
- An estimate of the affected patient population, similar derogation, an overview of the CA-s incl decision and reasoning, expected date that the CE certificate will be issued and timeframe confirmed by the NB, stock situation in combination with usage figures resulting in the number of days of stock at the most critical care providers, an overview of the customers with whom these risks will occur, timeline in which these risks are expected, an explanation of whether the MD can replace in short term by other MD from other MF incl explanations, a confirmation that the products covered by this application for derogation have not been adapted/changed after the CE certificate has expired and will be produced and delivered under exactly the same conditions in the event of a possible derogation, if CE certificate has already expired, proof that customers/healthcare institutions have been informed about the invalidity of the CE certificate
- The medical reason for the need of the device, amount; alternatives, previous CE status, etc
- MDR transition/notified body status, but this is not a prerequisite for an A59 derogation
- If device marketing/use/available outside the EU/EEA, number of devices, specification on when the device is expected to be CE marked, if the device has been used before in clinical trials or performance studies, how the device differs from other similar devices already on the market, explanation on the documentation that provides support for the device to be used safely and correct for both the patient and other users, details on vigilance or recall issues to date, indication on what measures have been taken to find an alternative device that meets the requirements of the regulations, explanation why any available CE-marked device(s) or are not a suitable alternative for the patient(s), describe possible consequences if the patient(s) cannot access the device(s)

Other reasons for derogation

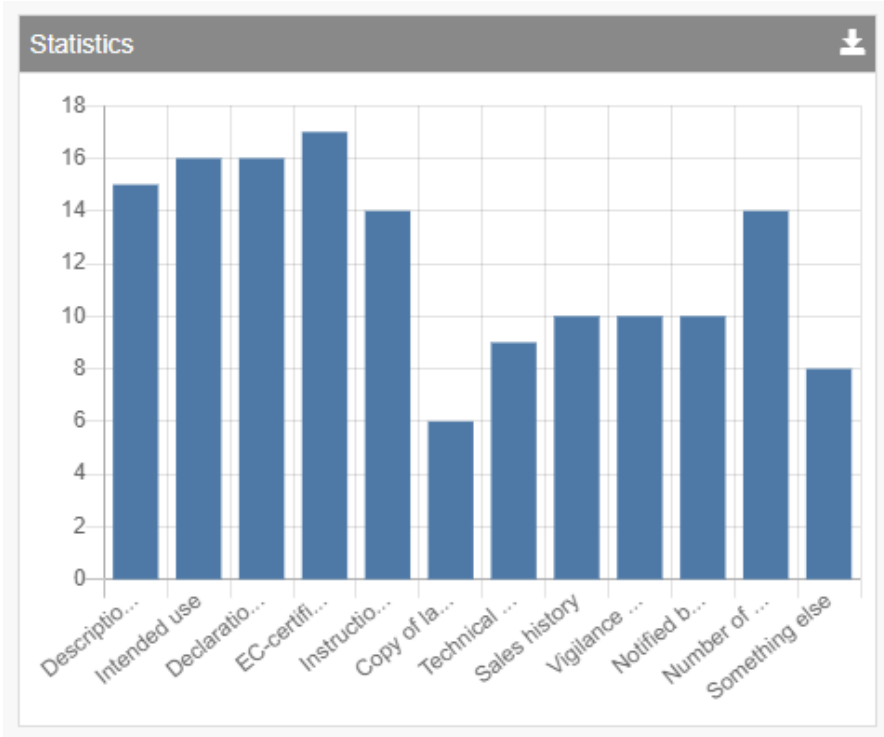
- Statement that the device has no alternative on the national market, device does not pose an unacceptable risk to public health and patient safety, evidence that the device fulfills the general safety and performance requirements, taken into account the intended use, (if available) the market authorisation status of the device in other countries, written opinions of health institutions and organisations or their competent authorities on the neccesity of the device, including the reasons why the device cannot be supplied
- The number of medical devices to be supplied under the exemption and the list of end-users, documentation demonstrating the need for placing the device on the market, need for the medical device concerned, evidence that there is no equivalent alternative on the market (or equivalent device or other treatment), an explanation of how the device concerned differs from others on the market, market share, availability of the device, information on the regulatory status of the medical device, certificates, notifications, declarations valid outside the EU (certified copies of documents), information on regulatory status in other EU other Member States have granted/refused derogation or still in the process – not yet completed, conformity history of the device – whether the device had CE marking, certificates, declarations in the EU before the new Regulation came into force, whether the device is intended for certification for the EU market or is already in the process of certification (evidence that the manufacturer and the notified body have signed the contact, and that the assessment procedure is ongoing), whether critical parts of the device have already been assessed and demonstrate an adequate level of safety for the user or recipient (patient), confirmation general safety and performance requirements, data on clinical studies/testing, an indication when certification under the MDR by a notified body is supposed to be concluded
- Applicant provides all the safety guarantees
- Justification as to why the conformity assessment procedure has not been completed, details incl proof of the planned completion of the conformity assessment procedure, evaluation of potential alternative devices and/or therapeutic procedures, justification as to why the placing on the market/putting into service of the devices are in the interests of public health or patient safety or health, number of devices placed on market in the last 3 years, estimated number of MD under the derogation, list of customer, proof general safety and performance requirements

In summary: other reasons for derogation

- Alternative devices or treatments
- General safety and performance requirements
- Statement of the Notified Body
- Differs explanation from others on the market
- Data on clinical studies/trials/performance studies
- List of customers
- Affected patient population
- Stock, market situation

What supporting documents do you ask for...

		Answers	Ratio
Description of the device		15	78.95 %
Intended use		16	84.21 %
Declaration of conformity		16	84.21 %
EC-certificate(s), if applicable		17	89.47 %
Instructions for use		14	73.68 %
Copy of labelling/device package		6	31.58 %
Technical documentation		9	47.37 %
Sales history		10	52.63 %
Vigilance reports		10	52.63 %
Notified body evaluation		10	52.63 %
Number of devices made available under the derogation		14	73.68 %
Something else		8	42.11 %
No Answer		2	10.53 %



Other supporting documents

- Documentation based on provisions laid down in Annex II, III and IV of Regulation (EU) 2017/745, up-to-date and complete to the maximum extent incl. a justification as to why a particular part of the documentation was not submitted
- Risk and vigilance assessment
- One or more user(s) or healthcare provider(s) to explain the effect on patient care or patient safety if the derogation is not granted and to declare that no equivalent
- Risk analysis, countries where placed on market, statement from healthcare professional
- Full technical documentation is not requested in all circumstances
- Statement that the device has no alternative on the national market, statement that the device does not pose an unacceptable risk to public health and patient safety, evidence that the device fulfills the general safety and performance requirements, taken into account the intended use, (if available) the market authorization status of the device in other countries, (if available) written opinions of health institutions and organisations or their competent authorities on the neccesity of the device, including the reasons why the device cannot be supplied
- Additional requests for information on case by case
- Case by case, request the latest EC declaration of conformity issued by the manufacturer and we request a declaration of conformity to the general requirements, part of the technical documentation may be requested, sales history-especially history of use, in certain cases, it may be asked to identify current certification problems

Other supporting documents

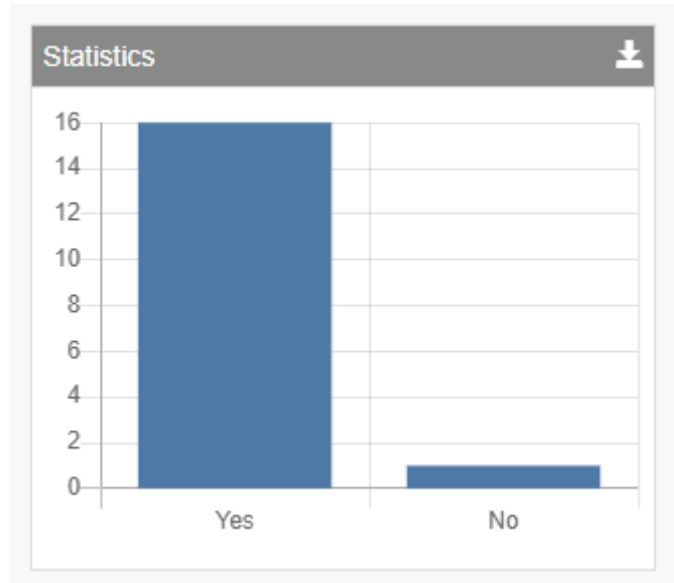
- Regarding the number of devices depends if derogation is granted on number of units or with a timeframe
- It depends on the situation/product what we ask for
- Any decisions already given by other EU member states/marketing authorisations in other jurisdictions, if the certificate is still valid, plan to put devices on the market before the certificate expires in order to build up stocks? explanation and details, if applicable, of alternatives for each device, for a device previously placed on the market, the list of customers (name, address) and the list of the number of devices ordered for each customer (name and reference) over the last 3 years, a proof that there is a quality management system in place, provide the date of the last surveillance audit report, confirmation letter by the notified body that application for MDR certification has been accepted and the contract signed with the manufacturer, commitment by the notified body to inform the CA about major safety-related shortcomings identified during conformity assessment, a detailed roadmap for obtaining the new certificate, reinstating the suspended certificate (if applicable), provide a report containing relevant data gathered through its post-market surveillance (PMS) system, in particular data concerning incidents, serious incidents and/or field safety corrective actions, should based on these elements the benefit-risk ratio is still positive, provide information about potential safety-related shortcomings identified by notified body during last surveillance audit and confirmation regarding satisfactory resolution

In summary – conclusions on the reasons for derogations and supporting documents

- It appears like duplicate questions for respondents
- Question of supporting documents was presented in general terms, but the respondents have gone into detail in their answers, presented the content that is asked in the following separately questions
- It appears that the entire tehnical documentation is not being requested
- The procedure is carried out on a case-by-case basis

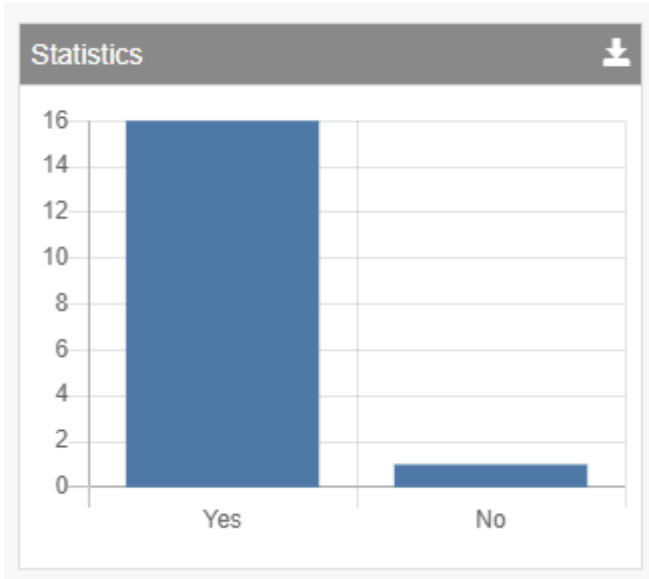
Do you ask about similar applications in other EU countries?

		Answers	Ratio
Yes		16	84.21 %
No		1	5.26 %
No Answer		2	10.53 %



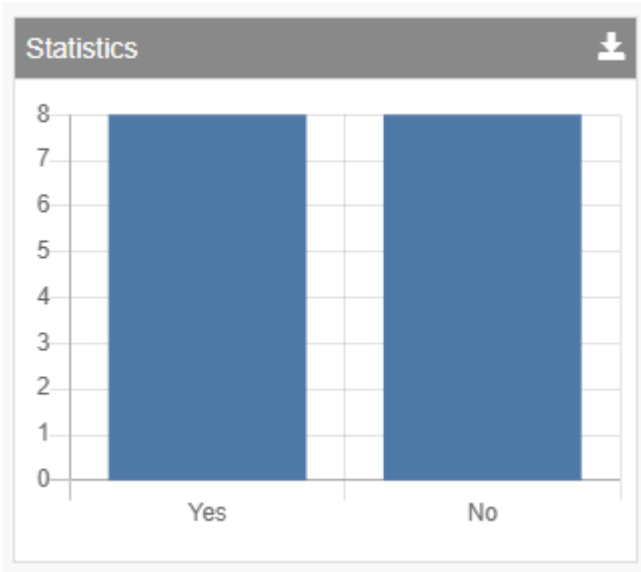
Does the healthcare institution/professional user also justify the derogation?

		Answers	Ratio
Yes		16	84.21 %
No		1	5.26 %
No Answer		2	10.53 %



Do you also ask the applicant to confirm or take responsibility that it is a non-compliant medical device?

		Answers	Ratio
Yes		8	42.11 %
No		8	42.11 %
No Answer		3	15.79 %



Approximately how many national derogation requests do you receive/approve/reject per year?

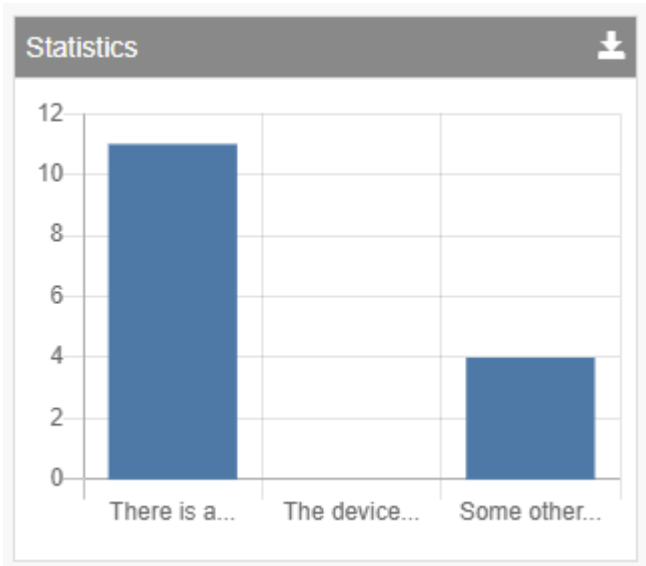
Country	Receive	Approve	Reject
1.	ca 14	Ca 7	Ca 7
2.	5-10	4-9 (ca 90%)	1-2 (ca 10%)
3.	-	-	-
4.	0	0	0
5.	20	16	3-4
6.	12-13	10	2-3
7.	10	8	2
8.	10-15	10-15	0
9.	4	0	4
10.	15	10	0

Approximately how many national derogation requests do you receive/approve/reject per year?

Country	Receive	Approve	Reject
11.	5	2	3
12.	3-4	3-4	0-1
13.	50	29	8
14.	1	1	1
15.	10	9	1
16.	3	3	0
17.	20-30	23	2
18.	15	13	2
19. Annual report 2022	26	13	?

If rejected, what is the most common reason?

		Answers	Ratio
There is a suitable alternative		11	57.89 %
The device is unsafe		0	0.00 %
Some other reason		4	21.05 %
No Answer		6	31.58 %

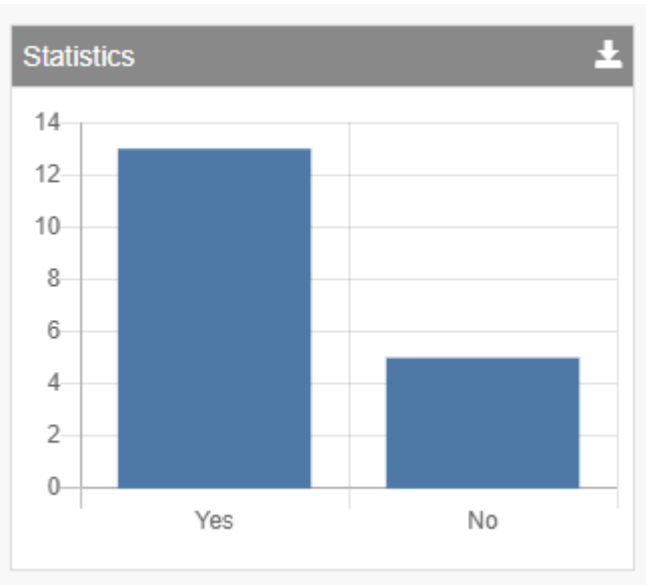


Other reason

- No support of healthcare professional
- There is no safety information on the device (device not yet marketed)
- Mainly for failure to provide the necessary documents
- That on a overall assessment the interest of public health or patient safety or health cannot be justified
- Device intended for clinical study
- Lack of positive benefit/risk data

Have you had any cases where the applicant has withdrawn the application or failed to complete the process?

		Answers	Ratio
Yes		13	68.42 %
No		5	26.32 %
No Answer		1	5.26 %



Reason for withdrawal or failure to complete process

- Perhaps because the device was unsafe
- Devices have availed of amended transitional provisions to MDR
- Transitional provisions, change of market situation
- Withdrawn as a result of an EU exemption or the applicant was not entitled to apply for an exemption
- The applicant is not able to fullfil the requirements
- Unknown
- Not sufficient supporting documents
- Adoption of Reg 2023/607, prolonged validity of MDD certificate
- When the request comes from the healthcare professional but the manufacturer does not wish to follow this procedure, or when the applicant agrees to follow our proposal to set up a clinical investigation
- Failure to submit sufficient evidence
- Costs
- The reasons are different for every case but it happens when sending them a first round of questions, assuming that they realize that they don't comply with the derogation requirements

Fees

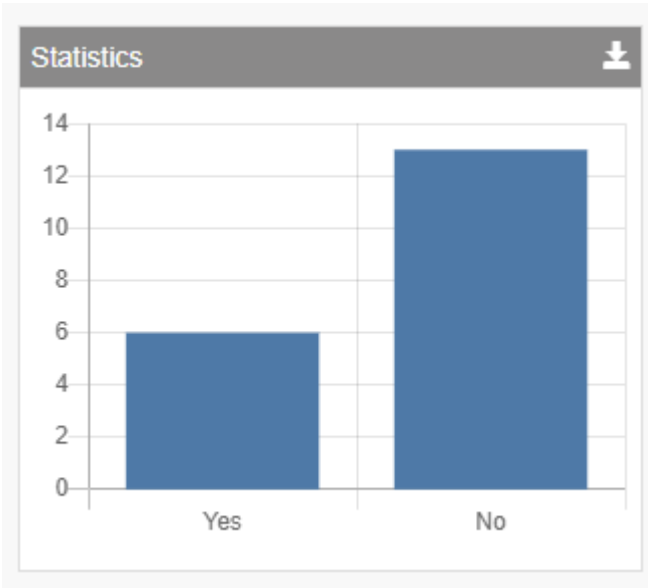
Country	Fee amount
1.	250-10.300 EUR (acc. to nat. fee ordinance)
2.	Not yet
3.	It is written in the national law that we can ask for a processing fee, however we are currently not asking for a derogation processing fee
4.	4000e, which may be waived at CA's discretion
5.	1.084,67 Euro
6.	The fee varies between 1930€ - 4070 €
7.	There's no fee for derogation procedure, just fee for General administrative procedure (22,66 EUR)
8.	the hourly price is 200 francs
9.	1000 euro
10.	193 Euro per hour
11.	Not yet
12.	62000 SEK

Compassionate use/single patient derogation

MDR 2017/745 Article 59
IVDR 2017/746 Article 54

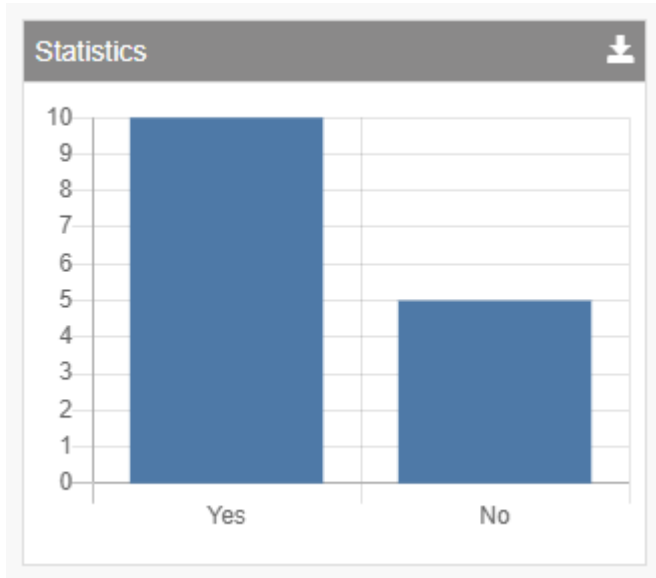
Is the procedure for making derogation laid down in national law?

		Answers	Ratio
Yes		6	31.58 %
No		13	68.42 %
No Answer		0	0.00 %



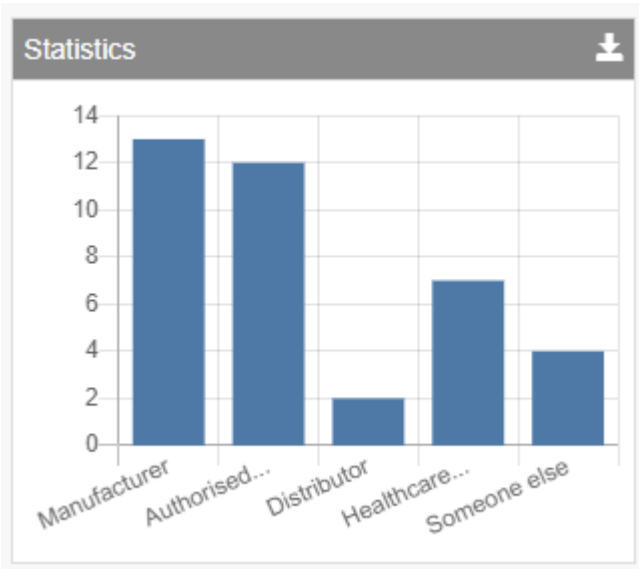
Do you have standard application/request templates?

		Answers	Ratio
Yes		10	52.63 %
No		5	26.32 %
No Answer		4	21.05 %



Who can apply for a derogation?

		Answers	Ratio
Manufacturer		13	68.42 %
Authorised representative		12	63.16 %
Distributor		2	10.53 %
Healthcare institution/professional user		7	36.84 %
Someone else		4	21.05 %
No Answer		4	21.05 %

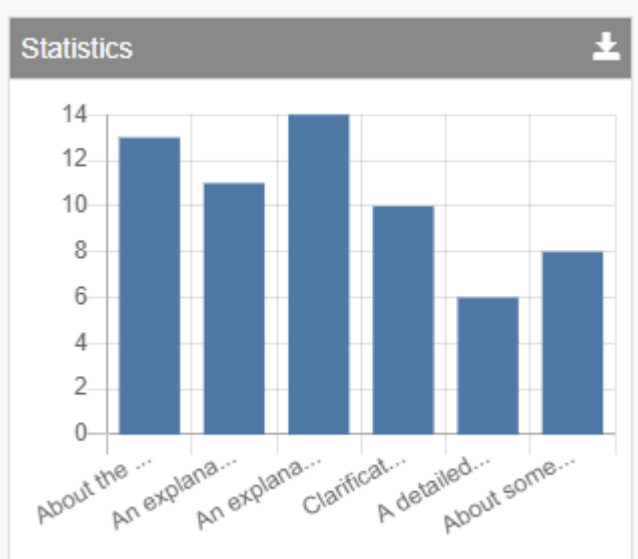


Someone else who can apply

- Who wants is not determined
- Dual application from manufacturer/authorized rep and appropriate specialist needs to be submitted
- All the other if authorized by the manufacturer
- The healthcare professional justifies the public health interest
- It is not determined by law who is allowed to apply for a derogation
- Any person duly mandated by the manufacturer or authorized representative (a copy of the mandate has to be provided)

When you ask about the reasons for the derogation, do you ask...

		Answers	Ratio
About the non-conformity(ies)		13	68.42 %
An explanation why the compliance assessment has not been started or completed		11	57.89 %
An explanation why the use of a medical device is vital		14	73.68 %
Clarification on the period for which the derogation is requested		10	52.63 %
A detailed plan on how to ensure compliance or withdrawal of the device from the market after the temporary derogation expired		6	31.58 %
About something else		8	42.11 %
No Answer		4	21.05 %

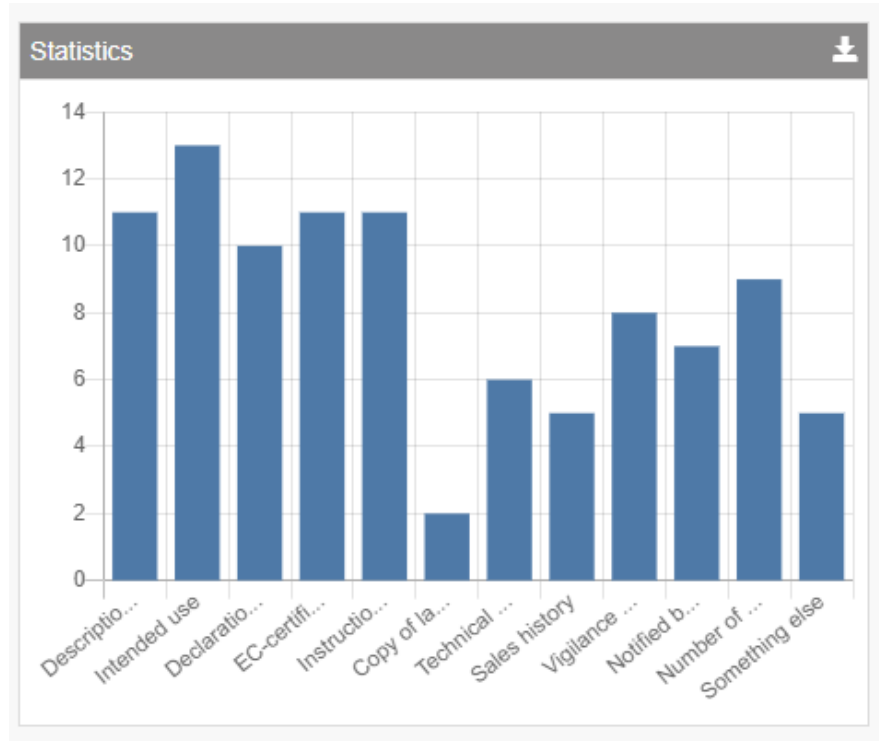


Other reasons for derogation

- Medical expertise about the essentiality of the device. Conformity to the essential safety and performance requirements. Approval or certification in other industrial states worldwide. Experiences in human use / animal studies. Current, completed or planed clinical trials.
- An explanation of the potential risks for the patient, a consent of the patient, stating the patient agrees to the use of the non-certified medical device, a statement declaring there is no suitable alternative in Europe.
- The medical reason for the need of the device; amount; alternatives; previous CE status, etc.
- Same standard request template as national derogation procedure.
- Additional explanations are requested case by case.
- If an equivalent CE marked medical device is available on the Union market, an explanation on what differentiates the non-CE marked device from equivalent CE marked Devices, the clinical benefit- risk assessment for the patient using the device.
- name of the required medical device, including any accessories+justification of the extent to which the use of the medical device is warranted in the interest of health protection+evidence of the lack of availability of equivalent medical devices for which the conformity assessment procedures have already been carried out+confirmation of compliance with the essential safety and performance requirements applicable to the medical device, taking into account its intended purpose. Where certain essential safety and performance requirements are not fully complied with, a detailed benefit/risk assessment demonstrating that the use of the medical device is appropriate despite this partial non-compliance and that, with regard to the requirements not fully complied with, all necessary measures have been taken to protect patients, users and, where applicable, third parties.
- It is the same as for the other derogations.
- Are there similar CE-marked devices? / If so, why can’t they be used? / Are there alternative treatments (medical devices, medicines or other treatments)? / If so, why can’t they be used? / Has the device been approved by the FDA? / If so, what is the intended purpose of this device ? / Is the device undergoing clinical investigation - performance study? / If so (ongoing or finished), What is the study title ? / If so (ongoing or finished), What is the complete scope ? / If the clinical investigation / performance study is still ongoing, is it located in Belgium ? / If so, why can’t the patient / patient sample be included in the study ? / A special form has to be filled-in by a physicien (sex, age, medical condition, medical reason for the application / consequence if the device is not used, date of the surgical intervention, is there similar devices or treatment, why they can't be used)

What supporting documents are you asking for...

		Answers	Ratio
Description of the device		11	57.89 %
Intended use		13	68.42 %
Declaration of conformity		10	52.63 %
EC-certificate(-es)		11	57.89 %
Instructions for use		11	57.89 %
Copy of labelling/device package		2	10.53 %
Technical documentation		6	31.58 %
Sales history		5	26.32 %
Vigilance reports		8	42.11 %
Notified body evaluation		7	36.84 %
Number of devices		9	47.37 %
Something else		5	26.32 %
No Answer		5	26.32 %

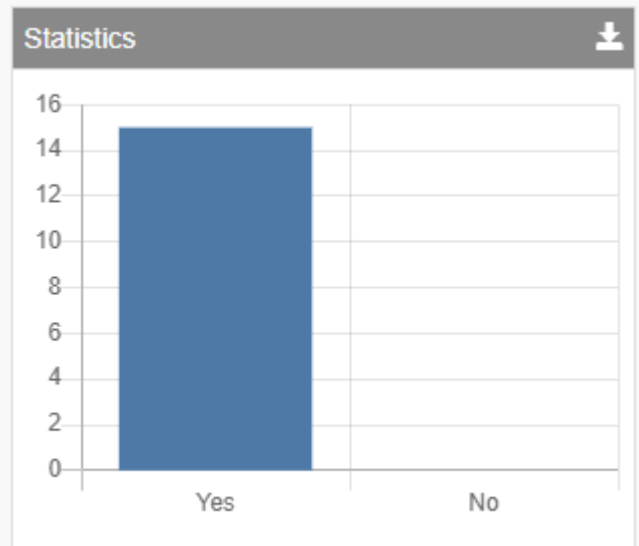


Other supporting documents

- A request under article 59 MDR must contain all the following elements, identification of the hospital(s) and physician(s) responsible for the use of the device, duly justified grounds for the delivery of the non-CE marked device, a medical justification (by the hospital) for the use of the medical device in question, including the nonexistence of an alternative CE marked device, and/or the non-suitability of alternative techniques/procedures, authorization from the Executive Board of the hospital(s) where the procedure will take place, the opinion of the Health Ethical Committee of the aforementioned hospital(s)
- Patient consent
- A copy of the chamber of commerce, an explanation of the potential risks for the patient, a consent of the patient, stating the patient agrees to the use of the non-certified medical Device, a statement declaring there is no suitable alternative in Europe, a doctors statement
- Risk analysis, countries where placed on market, statement from healthcare professional
- Supporting documentation may be tailored to the requirements of the specific application
- The assessment is made on a case-by-case basis, the most important thing is that the applicant provides us with all the safety guarantees available
- Depending on the case, healthcare professionals can help to justify the public health interest involved
- Application is relevant to a non CE marked device, documents verifying the performance of the non-CE marked device, if the concerned device includes materials for manufacture which are derived from animal origin (excluding devices which contain material of animal origin which are externally applied and are not placed in contact of broken skin)

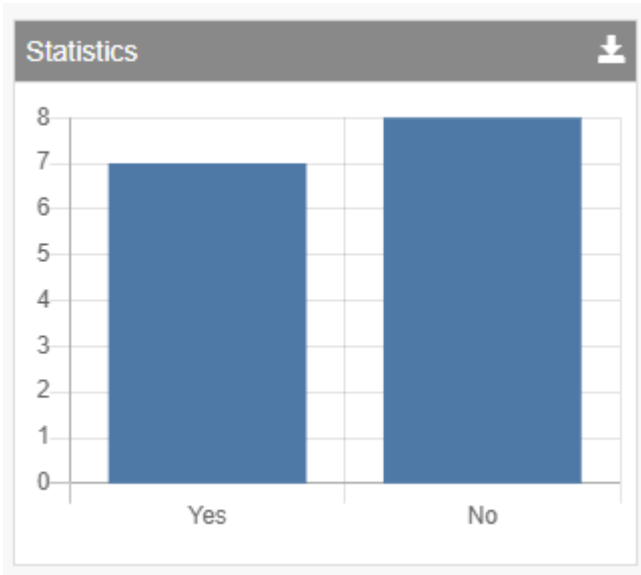
Does the healthcare institution/professional user also justify the derogation?

		Answers	Ratio
Yes		15	78.95 %
No		0	0.00 %
No Answer		4	21.05 %



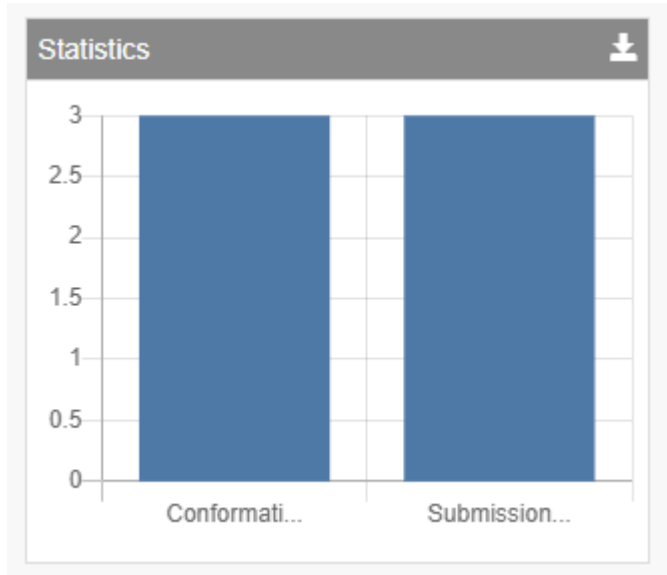
Do you want to know that the applicant has informed the patient of the non-compliance?

		Answers	Ratio
Yes		7	36.84 %
No		8	42.11 %
No Answer		4	21.05 %



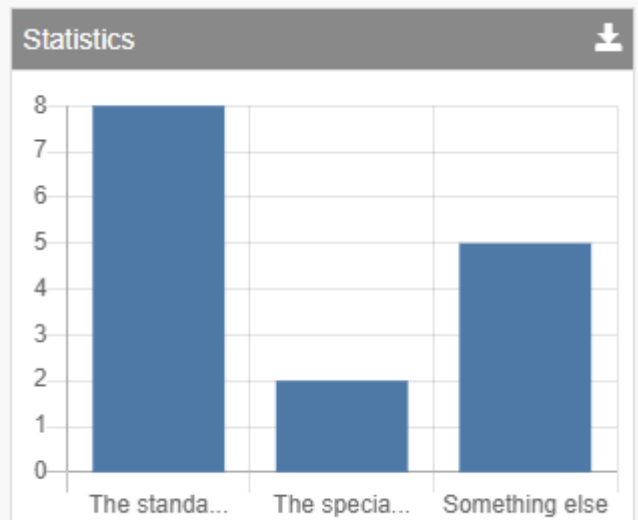
If you answered **yes** to the previous question, do you require as proof either of the following:

		Answers	Ratio
Conformation by the healthcare professional/applicant that the patient or the patient's representative has been informed		3	15.79 %
Submission of an informed consent form signed by the patient or the patient's representative		3	15.79 %
No Answer		15	78.95 %



If it is an **urgent request** situation for compassionate/single patient use do you apply...

		Answers	Ratio
The standard procedure		8	42.11 %
The special procedure		2	10.53 %
Something else		5	26.32 %
No Answer		4	21.05 %



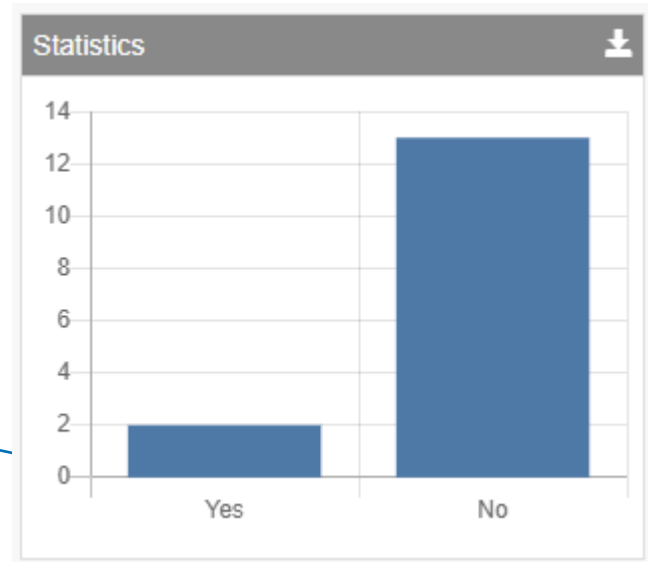
Urgent request situation

- The case gets a higher prioritization, but the standard procedure will apply as well
- In very rare case we grant a compassionate use after the surgery, in this case, the applicant must demonstrate that it was not possible to fill-in an application before the surgery due to the emergency
- Urgent request situations require an individual risk benefit assessment, medical opinion on the essentiality of the device
- The special procedure, less documents, not full tehnical documentation
- The health care professional's statements is most requested
- Standard procedure is completed urgently in these cases
- CA initiates on its own motion necessary measures to clarify the case sufficiently, an explanation why the use of a medical device is vital, details on vigilance or recall issues to date, substantiation to support the risk/benefit-analysis
- Informing the patient, in cases of vital emergency, authorization is granted on the basis of a template mail and restricted elements
- Request for information on the absence of alternatives available in view of the life-threatening emergency to be identified (ex : artifial heart)

Have you established a minimum number of days between the submission of your application and the decision on the application?

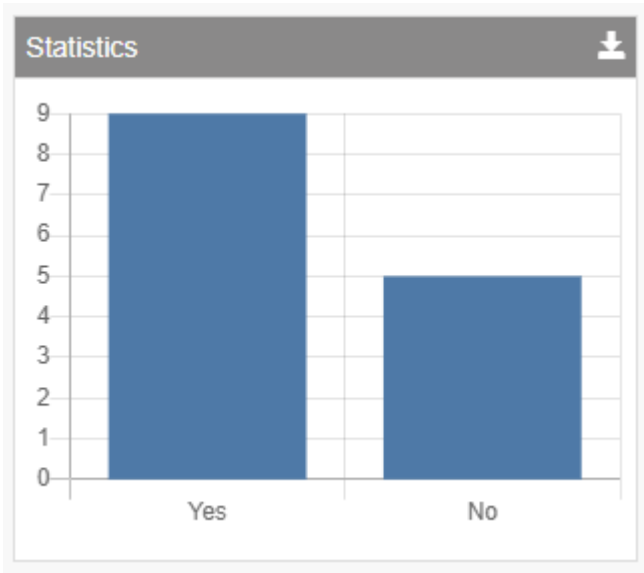
		Answers	Ratio
Yes		2	10.53 %
No		13	68.42 %
No Answer		4	21.05 %

Some procedures have been processed in less than 24 hours
30 calendar days



Do you also ask the applicant to confirm or take responsibility that it is a non-compliant medical device?

		Answers	Ratio
Yes		9	47.37 %
No		5	26.32 %
No Answer		5	26.32 %



Approximately how many compassionate/single patient use derogation requests do you receive/approve/reject per year?

Country	Receive	Approve	Reject
1.	-	-	-
2.	8	8	0
3.	100-150	App 90%	App 5%
4.	1	0	0
5.	3	2-3	1
6.	2-3	2-3	0
7.	25	24	1
8.	2	2	0
9.	-	-	-
10.	15	10	0

Approximately how many compassionate/single patient use derogation requests do you receive/approve/reject per year?

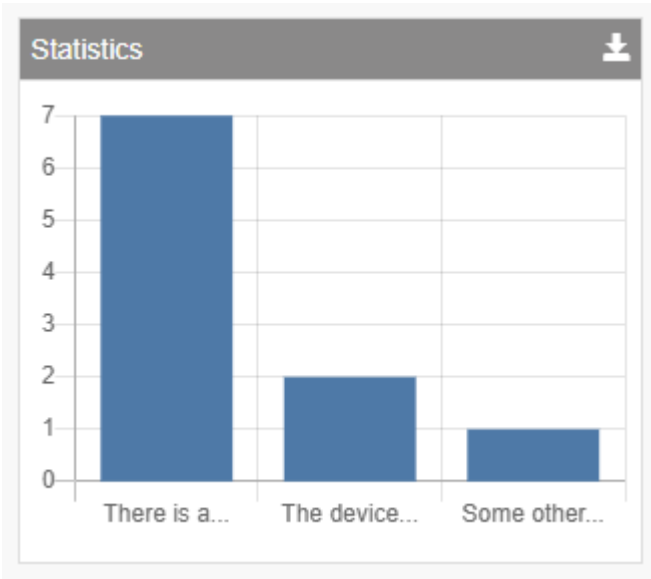
Country	Receive	Approve	Reject
11.	2	2	0
12.	Compassionate use/ single patient use is not defined in EU legislation or in national law.		
13.	36	26	2
14.	-	-	-
15.	0	0	0
16.	6	5	1
17.	0	-	-
18.	3-5	3-5	0
19.	63	62	1

If rejected, what is the most common reason?

		Answers	Ratio
There is a suitable alternative		7	36.84 %
The device is unsafe		2	10.53 %
Some other reason		1	5.26 %
No Answer		11	57.89 %

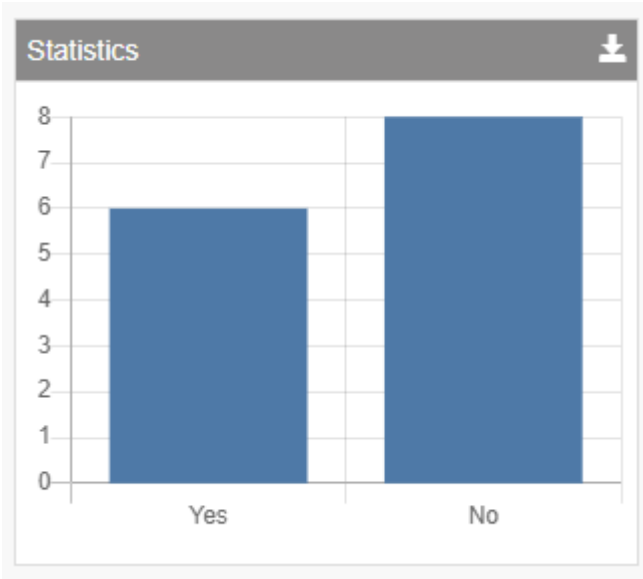
Inadequate information, including testing, was provided to enable a benefit-risk assessment compared to alternative treatments.

Lack of positive benefit/risk data.



Have you had cases where the applicant has either withdrawn the application or failed to complete the process?

		Answers	Ratio
Yes		6	31.58 %
No		8	42.11 %
No Answer		5	26.32 %



Reason for withdrawal or failure to complete process

- Not all required elements were submitted by the applicant
- Different
- We do not know
- Compassionate Use not applicable
- Wrong department (did not turn out to be compassionate Use)
- Adequate documentation was not provided to enable adequate assessment
- Death or use of another emergency technique, when the request comes from the healthcare professional but the manufacturer does not wish to follow this procedure

Fees

Country	Fee amount
1.	Currently, no
2.	250 - 10.300 EUR
3.	500 Euro
4.	193 Euro per hour
5.	62000SEK
6.	The fee varies between 1930€ - 4070 €

Useful information/experience

- Usually authorisations under article 59 MDR are under the premise "one device (unit), one hospital/patient". Exceptionally, authorisations are granted to several units of one device for one hospital. We do not grant national-wide authorisations, as we consider these to be exceptional situations and also because, as we have already referred in one of the previous answers, the manufacturer must submitted elements which are produced by each hospital where the non-CE marked device will be used
- Art. 59 is essential because it makes it possible to treat patients with not certificated devices based on individual cases and to act against device supply shortages. Applicants and users reveal a high grade of responsibility using the possibilities of Art. 59
- Application forms really help with setting expectations as well as rising the bar for an application just enough so that only serious applications come in
- Important national competence and there is a large expectation in our health system for such a service, there are considerable resource expertise and governance considerations for CA's processing derogations
- Processing of the requests is found to be very time consuming and laborious
- It is almost impossible to identify equivalent medical devices which are CE-marked (we do not expect EUDAMED to solve this problem utterly)
- Ggood experiences, some difficult questions in the context of manufacturer not willing to receive CE-marking for their products (MDR).

Future plan -What do you think should be changed in the derogation procedure?

- Filling the CIRCABC derogation table is sometimes problematic, because the table is sometimes checked out an other states are not able to deliver the data any more
- An established procedure and a specific form for this purpose with both derogations
- In the process of aligning our internal procedure, on EU level, maybe there should be a guidance to ensure uniformity of handling and assessment of the applications and that outlines "interest of public health or patient safety or health"
- Optimal application of the procedure would benefit from greater visibility with regards expectations and documents expected between MS's, in addition, there is currently no clear visibility or established procedure for extending a national derogation to Union wide level under A59(3), would like to review the use of derogations with other MS's and explore the most appropriate use of A59(3), for example in a coordination call
- Currently it is free to apply for a derogation, handling derogation invest a lot of time and resources, it should be the manufacturer/ applicant who pays for the deviation from conformity, not the general tax payer

Future plan -What do you think should be changed in the derogation procedure?

- It should be harmonised for all CAs
- The application form should be updated to save time during the examination phase
- Process development is ongoing
- Not sure that 100% of the derogation are uploaded on Circa, would be useful to also upload refusal and the reasoning behind, it could be done via a modification of the art. 59.2. due to the “notified body bottleneck” there are more and more derogation request due to a too long certification procedure are shortages on the market, it was not the initial goal of the art. 59 and in some cases it could be seen as a shortcut to the certification process, eudamed was foreseen as a central tool of the legislation, it should have been useful for derogation, for example via an easy access to the certificate and a list of the similar devices that are on the market, need to have Eudamed as soon as possible, it seems that the criteria’s used to grant a derogation vary among EU Competent authorities, the duration of the derogation varies in each country
- Consider to introduce a common standard EU/EEA-template for the derogation process

REPUBLIC OF ESTONIA
HEALTH BOARD

Thank you for replying

Your input was very helpful

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