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INTERTEK MEDICAL NOTIFIED BODY (IMNB)
REGULATORY SUMMIT 18TH OF MARCH 2021
Short about the IMNB organisation
MDR Transition
How to apply under the MDR
Presenter: Curtis Riley, Interim Head of Notidied Body for:
Intertek SEMKO AB, NB 0413 (MDD)
Intertek Medical Notifed Body AB, NB 2862 (MDR)
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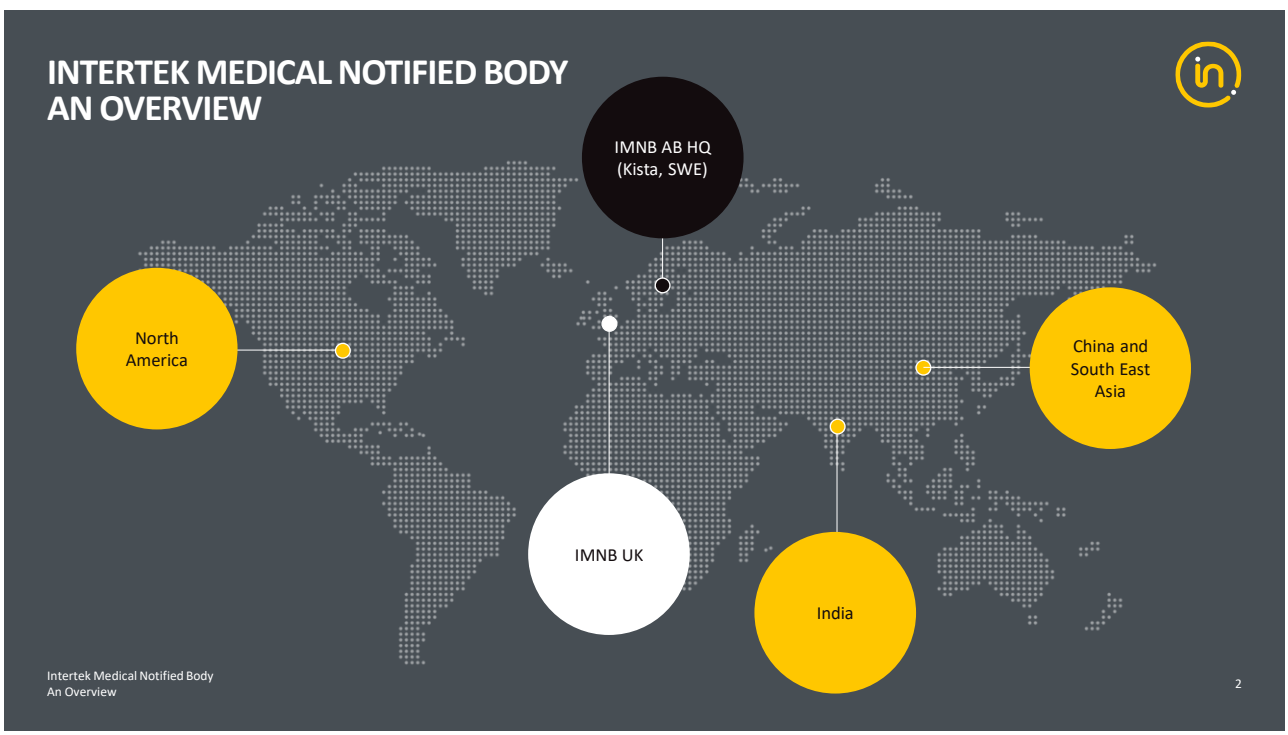
INTERTEK MEDICAL NOTIFIED BODY
AN OVERVIEW
IMNB AB HQ
(Kista, SWE)
North
America
China and
South East
Asia
IMNB UK
India
Intertek Medical Notified Body
An Overview
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## CERTIFICATES SUBJECT TO TRANSITION FROM AIMDD/MDD TO MDR.

- All Medical Devices Notified Bodies (n=54) were invited to participate in the Eusurvey. The survey was closed on September 25 th . At that time, 34 Notified Bodies responded to the survey.*
- The objective of this survey was to provide transparency on Notified Bodies joint capacities to allow successful implementation of the MDR.
- Additionally, the survey addressed the number of certificates subject to transition from MDD/AIMDD to MDR during the 'soft transition period' between 2021 and 2024.

**The question regarding the certificates subject to transition from AIMDD/MDD to MDR was: « How many certificates will expire in the future?**

*Ref.: Team-NB-PositionPaper-ExpiringCertificates-20201209

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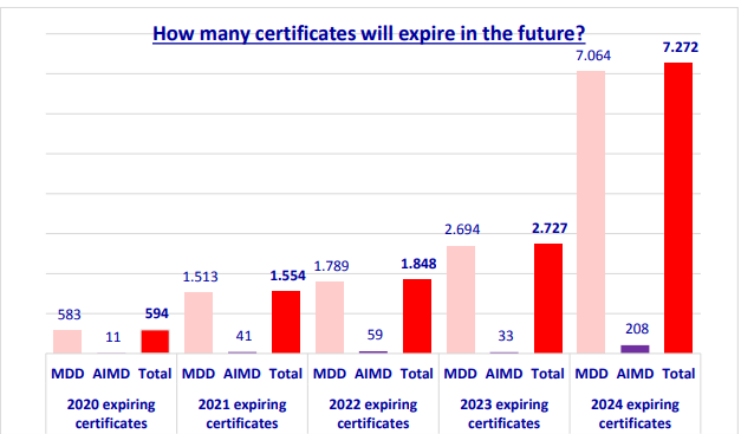
## CERTIFICATES SUBJECT TO TRANSITION FROM AIMDD/MDD TO MDR. HOW MANY CERTIFICATES WILL EXPIRE IN THE FUTURE BASED ON THE EU SURVEY ?




Ref.: Team-NB-PositionPaper-ExpiringCertificates-20201209

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## CERTIFICATES SUBJECT TO TRANSITION FROM AIMDD/MDD TO MDR.

- The distribution of certificates' expiration over the transition period of Directives certificates will be challenging.
- It is clear that in 2024, the number of expiring certificates will induce a peak in the workload of notified bodies that will be difficult to manage.
- It is time to consider solutions that will allow this peak to be distributed in order to manage it and to flatten the high waves in the workload of notified bodies in 2023-2024 to avoid risks for the public health.
- Taking into consideration the MDR certification process duration, an immediate solution is necessary, otherwise devices may not be available for patients.

- **The acceptance of remote audits under the Regulations will allow better progress in the transition from Directives to Regulations.**
- **Encouragement of manufacturers to continue to make progress with Regulation submissions, so that not all MDR submissions are made in 2024**

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## STATUS OF OUR MDD CLIENTS APPLYING FOR MDR


XX MDD cert exp 2021

XX MDD cert exp 2022

XXX MDD cert exp 2023

XXX MDD cert exp 2024


Around 40 of our current MDD clients have applied for MDR.

Around 140 new clients have applied.


**PLEASE Send your MDR application ASAP!**

STATUS OF OUR MDD CLIENTS APPLYING FOR MDR

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# MDR APPLICATION PROCESS

## How to apply?

Presenter: Curtis Riley, Interim Head of Notified Body

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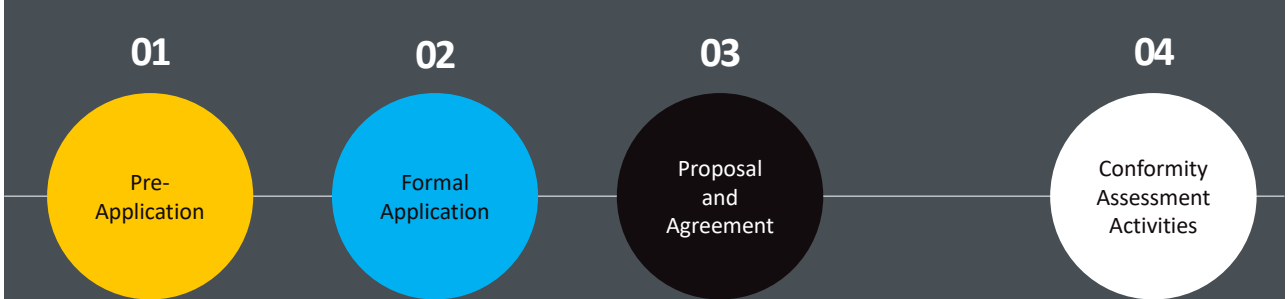
# MDR APPLICATION PROCESS AN OVERVIEW



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# MDR APPLICATION PROCESS

## 01 PRE-APPLICATION

- Before formally applying, you must* complete a pre-application form with basic information regarding your company and your device(s) that will be assessed and considered.
- The pre-application includes an option to request a formal application or a budget estimate which will be based on the information provided.

* This is optional for our current clients under MDD. Please contact us at IMNB@intertek.com for more information.

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## HOW TO APPLY FOR MDR CERTIFICATION

## 02 FORMAL APPLICATION

- If you opted for a formal application, we will send you a client information form (CIF). The CIF will ask you to provide further information about your company and devices. We will provide a guidance document to you on how to complete the CIF.
- If you opted for a budget estimate, we will send it to you separately.
- Your submitted CIF will be reviewed, and we may contact you to ask for further information or clarification.
- Please note that Intertek Medical Notified Body only accepts documentation in English.

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## HOW TO APPLY FOR MDR CERTIFICATION

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### PROPOSAL AND AGREEMENT

- After the CIF is assessed and approved by Intertek Medical Notified Body (IMNB), a proposal and certification agreement will be sent to you for consideration.
- The proposals and agreements are to be signed by you and countersigned by IMNB, and a copy is then sent to you by email. Please note: By signing the proposal you ensure that the legal address and scope of certification are correct. Any changes from your side after signing the proposal are to be handled separately.
- All aspects of the conformity assessment activities related to initial certification will be communicated separately to the client once the application is approved and agreements signed.
- Communication with IMNB regarding MDR should be sent to: IMNB@intertek.com

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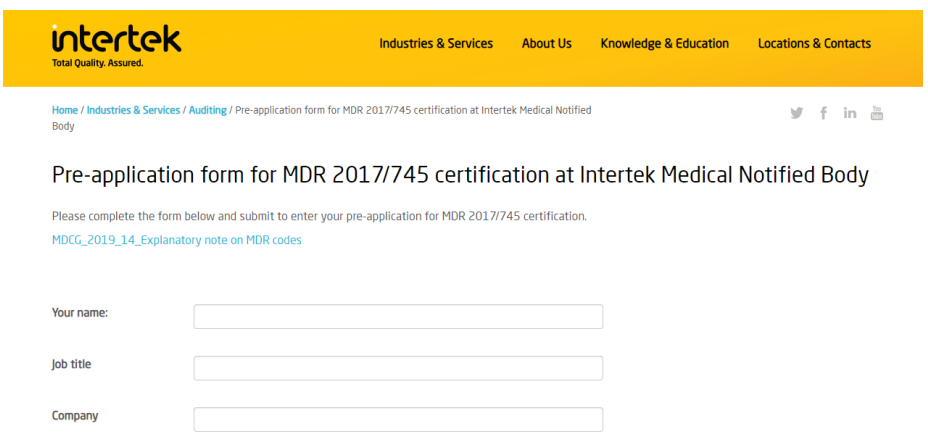
## HOW TO APPLY FOR MDR CERTIFICATION

Welcome to submit your pre-application for MDR 2017/745 certification on our webpage: https://www.intertek.com/auditing/mdr-pre-application/

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# INTERTEK MEDICAL NOTIFIED BODY

## REGULATORY SUMMIT 2021

**Covid-19 challenges from a Notified Body perspective**

18th of March
Remote
Presenter: Ella Helgeman, Quality and Regulatory Affairs Manager

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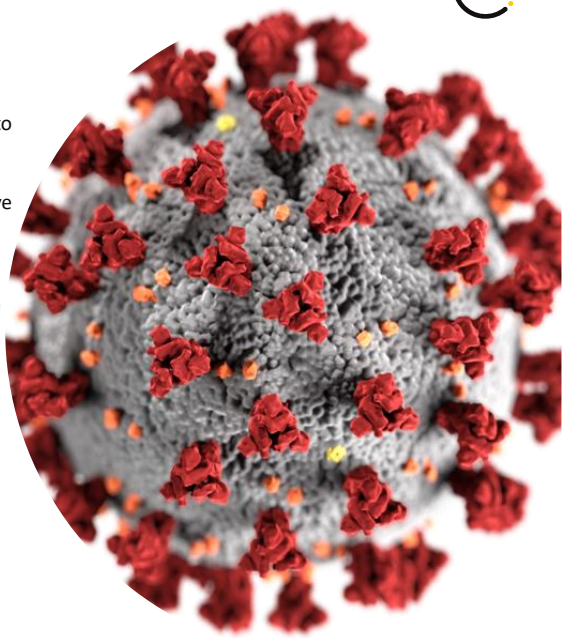
## COVID-19 CHALLENGES FROM A NOTIFIED BODY PERSPECTIVE

- Remote Audits under the MDD are performed following MDCG 2020-4
- Commission Notice 2021/C 8/01 for MDR Remote Audits
- Notified Bodies trade association (TEAM-NB) worked on a position paper to seek a harmonised approach within the member states to allow remote audits under the MDR.
- The uniform implementation of remote audits are not possible as MSs have different views concerning the implementation of the Commission Notice: *Commission Notice 2021/C 8/01 on remote audits under the Regulations (EU) 2017/745 and 2017/746 (MDR and IVDR).*
- Not possible to publish Team-NB position paper for harmonised approach
- New solutions needed – It is up to the member states to allow Remote audits under the MDR





## COVID-19 CHALLENGES FROM A NOTIFIED BODY PERSPECTIVE

Commission Notice 2021/C 8/01 on remote audits under the Regulations (EU) 2017/745 and 2017/746 (MDR and IVDR) is published , link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.2021.008.01.0001.01.ENG&toc=OJ%3AC%3A2021%3A008%3ATOC

IMNB emphasise that all requirements as stated in the Commission Notice 2021/C8/01must be followed:

- NB can perform a case-by-case assessment of individual circumstances, and to duly justify the individual derogations, and to not going beyond what is required.
- Notified bodies need to apply a risk-based approach, with the results duly documented and substantiated.
- Notified Body need to take decisions on certification limited to the time strictly necessary to allow for a proper on-site audit to be performed as soon as possible.

MPA will closely monitor the IMNB´s use of the temporary extraordinary measure and derogation as stated in the Commission Notice 2021/C8/01

Despite the Covid-19 Challenges, we are looking forward to support the manufactures with MDR Conformity assessment activities to ensure continuous availability of safe and performant devices on the market.

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# MDD APPROPRIATE SURVEILLANCE IMPLEMENTATION PLAN DURING GRACE PERIOD UNTIL MAY 2024

## Regulatory Summit 18th of March 2021

Presenter: Ella Helgeman, Quality and Regulatory Affairs Manager

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## CONSIDERATIONS FOR APPROPRIATE SURVEILLANCE BY NB DURING GRACE PERIOD UNTIL MAY 2024

| | |
|---|---|
| Regulatory Background<br>MDR, Article 120(3) | By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/ EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues to comply with either of those Directives, and provided there are No significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.<br><br>Without prejudice to Chapter IV and paragraph 1 of this Article, the **notified body** that issued the certificate referred to in the first subparagraph **shall continue to be responsible for the appropriate surveillance** in respect of all of the applicable requirements relating to the devices it has certified. |
| Further sources of information | • 2018-01: CAMD FAQ 17<br>• NB-med discussions, 2019-05 / 2019-10<br>• 2019-10: MDCG 2019-10 - Application of transitional provisions concerning validity of certificates issued in accordance to Directives 90/385/EEC and 93/42/EEC<br>• See also: Team NB Proposal for Appropriate Surveillance Audits |

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## CONSIDERATIONS FOR APPROPRIATE SURVEILLANCE UNTIL MAY 2024 - MANUFACTURER IS CERTIFIED UNDER MDD AND UNDER ISO 13485

| | |
|---|---|
| General considerations | • The audit cycles according to the certification rules of ISO 13485 need to be followed<br>• No significant changes are allowed |
| Audit | • The surveillance audits will cover all necessary elements of the QM system<br>➢ This includes, review of:<br>• Post Market Surveillance<br>• Vigilance<br>• Registration of Economic Operators<br>• Registration of Devices |
| TD Assessment | • TD Sampling –> Sampling of PSUR(s)<br>➢ This includes , review of:<br>• Conclusions of benefit-risk determination<br>  • Risk Management<br>  • Clinical Evaluation<br>  • State of the Art<br>• Information concerning serious incidents and FSCA<br>• Records referring to non-serious incidents and data on any undesirable side-effects<br>• Information from trend reporting<br>• Relevant specialist or technical literature, databases and/or registries<br>• Information including feedback and complaints provided by users, distributors and importers<br>• Publicly available information about similar medical devices<br>• Main findings of PMCF<br>• Volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and where practicable the usage frequency of the device |

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## IMNB REGULATORY NEWSLETTER

Newsletter is released every quarter and posted on Intertek's website:

https://www.intertek.com/assurance/mdr/

Medical Device Regulatory Updates Newsletter

**Stay up to date on Medical Device Industry news with our quarterly Regulatory Update newsletter.**

January 2021 Newsletter

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Do you have any questions?



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