REGULATORY SUMMIT, 18 MARS 2021

Question for Intertek Notified Body	Answers from Intertek Notified Bodý: Ella Helgeman, Regulatory and Quality Manager and Curtis Riley
TIPS FOR SPEEDY CERTIFICATION? What does an MDR CERTIFICATION COST “from scratch”? What is the WAITING TIME from application until certificate? For one product without a current N.B. and without any other certifications. Class IIa, IIb, III?	To achieve a speedier MDR certification we advise you to submit your MDR application sooner rather than later. It is important that you follow our CIFA guidance document, step by step, for how to submit your application and supply all the related documents. This will enable a speedier process to onboard you as a MDR client and to start the certification activities. The costs for MDR certifications is publicly available on our website: https://www.intertek.com/assurance/mdr-designation/ at the bottom of the webpage. It is difficult to provide the exact cost of for the MDR certification as this is depended on the quality of the documents supplied to the Notified body. The documents needs to be thoroughly reviewed and compliant with the MDR before you submit this to us. The factors that affects the prices is dependent on the product classification, type of device, amount of technical files and the size of the company and number of personnel. The best way to get an estimated cost would be if you complete the pre-application form and request a budget estimate by following this website: https://www.intertek.com/auditing/mdr-pre-application/ The waiting time from application until the MDR certificates gets issued could take from 6 months up to 12 months depending on the products.
Är Intertek notified body för specialanpassade engångsprodukter? OM reprocessing blir tillåtet behövs det för Vårdgivarna i Sverige	Intertek Medical Notified Body AB have concerns about the implementation of MDR Article 17 on the Swedish market. This is based on the risk for patients and we do not believe the benefit will be higher than the risk. However, If the Swedish government decides to allow this we will need to reconsider our role as a notified body in terms of this area.
When will your capacity be bigger? Your customer relationships are not good. It is impossible to get hold of you	Thank you for this feedback. Our aim is to provide speedier service and high client focus. Our customer relationship and service is essential for us. The best way to get in touch with us is to drop an email to our customer service team. Please make sure to send your request by email to: medtechsweden@intertek.com for MDD inquiries or IMNB@intertek.com for MDR Inquires. As we do face a lot of MDR application and many questions at the moment, we apologize if the lead times for responses is a bit longer than expected.
If reprocessing is approved, a Notified Body is required in accordance with implementing regulation 2020/1207. Are there any N.B accredited for this type of products today?	Intertek Medical Notified body is not designated for this this type of service based on implementing regulation 2020/1207 and does not have code MDT 2013 Devices which have undergone reprocessing in the MDR designation scope. As this is not allowed in Sweden today we conclude that there are no N.B accredited for this type in Sweden.
As we understand the path you present is exactly per the MDR requirements for a NB and as such the same for all NB?	The regulation stipulates the mandatory requirements which is applicable for all notified bodies. How these requirements are being implemented in the various procedures for Notified Bodies should more or less be harmonized for all.
During the transitional period, will the non-designated NB be responsible for reviewing MDR requirements also applicable for legacy devices (PSUR, SSCP etc)?	EDIT: 2021-05-12 If non-designated NB means ` non MDR designated` NB, the answer is: NB which issued the MDD certificate shall continue to be responsible for the appropriate surveillance of all the applicable requirements relating to the devices it has certified. Requirements for the placing on the market/putting into service of MDD compliant devices according to Art. 120 para 3 MDR after DoA are: Valid MDD certificate according to art. 120 para 2 MDR Continuous compliance of the device with the Directives No significant changes in the design and intended purpose of the device . The application of MDR requirements in place of the corresponding requirements of the Directives shall take place with regards to: - Registration of economic operators and of devices (see Art. 31 MDR and Art. 29 MDR) - Post market surveillance (PMS) see Art. 83-86, 92 MDR including Annex III but without the PMS having to be an integral part of the QMS - Market surveillance see Art. 93 – 100 MDR - Vigilance Art- 87-92 MDR. For legacy devices under class I (excluding Class Is, Ir and Im) the responsibility falls under the National Competent Authority, in Sweden this would mean that MPA is responsible for this surveillance and not the Notified Bodies designated under the MDD.