Questions and answers on medical devices and no-deal Brexit

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This FAQ contains questions and answers relevant to medical devices marketed in Denmark in case of a no-deal Brexit.

Marketing of medical devices

Question	Answer
What does placing on the market of a medical device mean?	Placing on the market means the first time a medical device, with the exception of medical devices intended for clinical investigation, in return for payment or free of charge is made available with a view to distribution and/or use in the EU/EEA. The European Commission has clarified that a medical device that is covered by a certificate issued by a UK notified body must be placed on the market before the date of a potential no-deal Brexit. This means that the device must be manufactured and that an agreement on the delivery of the device must have been concluded before the date of a potential no-deal Brexit. Please see the European Commission's Q&A for more information.

Questions and answers for manufacturers

Question	Answer
What will happen to medical devices that have been certified by a UK notified body and have already been placed on the EU/EEA market before the date of a potential no-deal Brexit?	If the device is already legally marketed in the EU/EEA before the date of a potential no-deal Brexit, it can still be distributed and used. Placing on the market means the first time a medical device, with the exception of medical devices intended for clinical investigation, in return for payment or free of charge is made available with a view to distribution and/or use in the EU/EEA. The individual device must have been made available to a recipient in the EU/EEA. The European Commission has clarified that products placed on the European market with a valid certificate from a UK notified body before a potential no-deal Brexit can still be distributed and remain in use after the Brexit withdrawal date. In other words, manufactured devices where an agreement on delivery has been concluded before a no-deal Brexit can remain in use. Conversely, physical delivery of the product is not required.
Is a medical device considered to be placed on the market if an agreement on	No. The concept of goods placed on the market implies that the

delivery of the device has been concluded, but the device has not yet been manufactured before a potential no-deal Brexit?	individual device must have been made available with a view to distribution or use in the EU/EEA.
What will happen to medical devices certified by a UK notified body and placed on the EU/EEA market before the date of a potential no-deal Brexit if they are still kept in stock (at the manufacturer, distributor, supplier or the like)?	Such devices can still be delivered and used provided an agreement on delivery has been concluded before a potential no-deal Brexit. As mentioned, the devices must be manufactured before the date of a potential no-deal Brexit.
Will the device need to be re-labelled when switching to a new notified body in the EU/EEA or transferring a certificate from a UK notified body to a notified body in the EU/EEA?	Medical devices manufactured and placed on the market after a potential no-deal Brexit must be labelled to ensure the new NB identification number has been indicated correctly on the labelling together with the CE-mark. The European Commission has stated that there is no need to re-label medical devices manufactured and placed on the market before the no-deal Brexit date. The device was legally marketed before the no-deal Brexit date, and it can still be distributed and handed out for use.
What should manufacturers do to ensure that devices certified by a UK authorised body can remain on the market and continue to be used in the EU/EEA in case of a no-deal Brexit?	You will need a new certificate from a notified body in the EU/EEA (via transfer/new application).
What can manufacturers do from the date of a potential no-deal Brexit to the time a new certificate from a notified body in the EU/EEA is obtained?	Until you get a new certificate, the device cannot be used in the EU/EEA. In special circumstances, the Danish Medicines Agency may, if health concerns speak in favour thereof, grant a time-limited authorisation to market and use a non CE-marked medical device in Denmark until a new certificate has been issued by a notified body in the EU/EEA. You must submit an application for authorisation to the Danish Medicines Agency. You can also seek exemption in other countries in the EU/EEA. You do so by applying to the competent authorities for medical devices in each of the respective countries.
What if our UK notified body is in the process of establishing a new notified body in the EU/EEA, but does not make it before a potential no-deal Brexit – what do we do then?	During this period, you will have no notified body in the EU/EEA. Consequently, the device cannot be used in the EU/EEA. In special circumstances, the Danish Medicines Agency may, if health concerns speak in favour thereof, grant a time-limited authorisation to market and use a non CE-marked medical device in Denmark until a notified body has been established in the EU/EEA and a new certificate has been issued. You can apply for such authorisation to the Danish Medicines Agency.

	You can also seek exemption in other countries in the EU/EEA. You do so by applying to the competent authorities for medical devices in each of the respective countries.
What if our UK notified body has been established in the EU/EEA before a potential no-deal Brexit – what do we do then?	You will need a new certificate from the notified body in the EU/EEA.

Exemption to market and use a non CE-marked medical device

Question	Answer
Can manufacturers seek exemption to be allowed to market a non CE-marked medical device?	Yes. Medical device manufacturers can apply for an authorisation/exemption from the Danish Medicines Agency. The manufacturer is not permitted to market a medical device that is not CE-marked without authorisation/exemption from the Danish Medicines Agency. Therefore, it is the manufacturer or his representative that must apply for authorisation/exemption.
How do we apply for an exemption to market and use a non CE-marked medical device?	In special circumstances, the Danish Medicines Agency may permit the marketing and use in Denmark of a medical device that does not have a valid certificate when health concerns speak in favour thereof. Manufacturers can apply for an exemption by completing and submitting an application form to the Danish Medicines Agency. The application form will be made available on the website of the Danish Medicines Agency in case of a no-deal Brexit.
When can we expect a decision to be made about our application?	The Danish Medicines Agency can make a decision on exemption no earlier than after the date of a potential no-deal Brexit. The reason is that medical device certificates issued by a UK notified body will remain valid as long as the UK is part of the EU/EEA.
What does the application involve?	You apply by submitting one application in two parts: • The first part is completed by the manufacturer. It identifies the manufacturer and provides information on the device as well as the status of the notified body in question. • The second part contains a statement from a healthcare professional/hospital/region. This statement is used to indicate if the device is necessary in patient treatment and whether it can be replaced by an alternative CE-marked medical device. The manufacturer obtains this information from the healthcare institution/region to fill out the second part of the application.
Is there anything manufacturers should do before applying for an exemption from the Danish Medicines Agency?	Before applying for authorisation, the Danish Medicines Agency recommends manufacturers to engage in dialogue with its UK notified body to get a status on their certificates in the event of a no-deal Brexit.

	If certificates are transferred to a notified body in the EU/EEA in time before the date of a no-deal Brexit, there is no need to apply for an exemption from the Danish Medicines Agency.
What will be given special attention to assess if health concerns speak in favour of the device?	The Danish Medicines Agency will pay particular attention to whether the healthcare professional/hospital states that the device is necessary for patient treatment. The assessment of the manufacturer's application will also take into account if there are alternative CE-marked medical devices on the market that serve the same purpose. Other circumstances may be relevant in the assessment, e.g. information on serious quality or safety problems with a specific device. The Danish Medicines Agency cannot grant exemption on the basis of other reasons, such as financial reasons.
On what legal basis is exemption granted?	The legal basis for exemption is provided in the following legislation: • Medical devices: ○ Executive Order no. 1263 of 15 December 2008 on medical devices, section 6(12) ○ Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, article 11(13). • In vitro diagnostic medical devices: ○ Executive Order no. 1269 of 12 December 2005 on in vitro diagnostic medical devices, section 6(11) ○ Council Directive 98/79/EEC of 27 October 1998 on in vitro diagnostic medical devices, article 9(12). • Active implantable medical devices: ○ Executive Order no. 1264 of 15 December 2008 on active implantable medical devices, section 5(8) ○ Council Directive 90/385/EEC of 20 June 1990 on active implantable medical devices, article 9(9).
For how long will the authorisation be valid?	The authorisation will be limited in time and will be determined for each individual application.

UK notified bodies

Question	Answer
Which UK notified bodies will be affected in case of a no-deal Brexit?	The identification numbers of the four UK notified bodies are: • NB 0086, BSI (UK) • NB 0088, Lloyd's Register Quality Assurance LTD (ceased) • NB 0120, SGS United Kingdom Limited

Questions and answers for authorised representatives

Question	Answer
Can authorised representatives seek exemption to market a non CE-marked medical device?	Yes, on behalf of the manufacturer. According to the definition of an authorised representative, the representative has been designated by the manufacturer to act on his behalf.

Questions and answers for importers and distributors

Question	Answer
Can importers and/or distributors seek exemption to market a non CE-marked medical device?	Yes, on condition that the importer/distributor has been mandated by the manufacturer to seek an exemption on behalf of the manufacturer. You can address the manufacturer who can apply for an exemption to market the device in Denmark. You can take the opportunity to ask if the manufacturer would be interested in authorising you to act on his behalf. If you are representing the manufacturer, a written power of attorney must be enclosed with the application to the Danish Medicines Agency.
What if the manufacturer of the device we are importing has a UK authorised representative – how do we handle this in case of a no-deal Brexit?	UK authorised representatives will no longer be able to act as representatives in the EU/EEA in case of a no-deal Brexit. The manufacturer is responsible for changing to an authorised representative established in the EU/EEA. Medical devices manufactured and placed on the market after a potential no-deal Brexit must be labelled to ensure the new authorised representative is indicated correctly on the labelling. There is no need for re-labelling. It is sufficient to add the information about the new representative in connection with the manufacturing of the device after the date of a potential no-deal Brexit. The European Commission has stated that there is no need to re-label medical devices manufactured and placed on the market before the no-deal Brexit date. The product was legally marketed before the no-deal Brexit date, and it can still be distributed and handed out for use.
What if the manufacturer of the device we are importing is headquartered in the UK– how do we handle this in case of a no-deal Brexit?	In case of a no-deal Brexit, UK manufacturers must have an authorised representative established in the EU/EEA. It is the sole responsibility of manufacturers to ensure they employ an authorised representative in the EU/EEA.