Client Newsletter

Medical Device Regulatory Updates

PUBLISHED MDCG GUIDELINES:

- There are new guideline documents published by MDCG which has impact on the industry. Please follow this link and perform impact assessment on your organisation.

WHAT IS THE FOCUS FROM EU-COMMISSION?

- Governance
  - ✓ Work on 70+ guidance documents ongoing or finalised
- Scientific structures
  - ✓ Establishment of expert panels, expert laboratories and reference labs
  - ✓ Expert panels operational Q4 2020
- Mandate for revision of standards
- Design and establishment of the new EUDAMED
- Establishment of UDI system
- Communication campaign
  - ✓ Dedicated website, factsheets in all EU languages and some major non-EU languages
- Planning of activities
  - ✓ Publication of Commission's rolling plan on DG SANTE website

Some critical issues:

- Availability of Notified Bodies
- Establishment of EUDAMED
- Timelines, resources and expertise

In addition:

- COVID-19
- International aspects: MRAs (CH, AU, NZ), Customs Union Agreements (TR), UK, unilateral CE-acceptance, trade agreements

EUDAMED ACTOR REGISTRATION IS PUBLISHED:

- The first module of EUDAMED: Actor registration was made available on 1 December 2020. The Commission is not in a position to require the use of the module until EUDAMED is fully functional according to the Medical Device Regulation (MDR) and additional national requirements on registrations can therefore not be excluded. We from Intertek Medical Notified Body recommend our clients to register and become familiar with EUDAMED.
- The Actor Module have 2 different sites.
  - Link to **Public** site: on this site you are able to search for Economic Operators which has been verified by the competent authority and received a SRN number
  - Link to **Restricted** site: The restricted site is mainly for the Economic Operator where they apply for an account, SRN and maintain their information.

  To be able to register an Economic Operator in EUDMED an EU Login Is required. If not yet obtained, please follow this link. The EU Login authentication service is a point for user authentication to a wide range of Commission information systems, EUDAMED included.

PRINCIPLES FOR DETERMINING ACTOR ROLES ACCORDING TO MDR AND IVDR:

The various roles in the supply chain have designated areas of responsibility with a scope that is adapted to the role, see for example Articles 10, 11, 13 and 14. In MDR / IVDR and other regulations, the actor roles are defined by how one acts with a certain product and / or a certain situation. The term "product" here refers to each copy of a product model. A natural or legal person could have all the actor roles according to MDR, ie. you can, for example, be a manufacturer, importer and distributor, if you handle different products and situations. You may also need to take on different roles according to different regulations.

- Factsheet for Authorised Representatives, Importers and Distributors of medical devices and in vitro diagnostic medical devices. Please follow link
- Factsheet for Manufacturers of medical devices. Please follow link

SWEDISH MEDICAL PRODUCT AGENCY - LANGUAGE REQUIREMENTS ACCORDING TO MDR AND IVDR

- The Swedish regulation (1993: 876) on medical devices has, through Swedish regulation 2020: 315, been supplemented with language requirements for information linked to medical devices according to MDR and IVDR on the Swedish market.
  The basic principle is that users must have access to information in Swedish, while information to be provided to the Medical Products Agency must be in Swedish or English.

  Documents which shall be in Swedish are:

- Safety message to the market (FSN) must be in Swedish
- The information about implants that the manufacturer must provide in accordance with Article 18 (1) of the MDR must be in Swedish. However, the information in the implant card as referred to in the third subparagraph of Article 18 (1) may also be English.
- The summary of a clinical trial that must be submitted as part of the application (according to section 3.1.5 in Chapter II of Annex XV to MDR) must be in Swedish.

The Medical Products Agency may continue to grant exemptions in exceptional cases.

NOTIFIED BODIES ENCOURAGE APPLICATION AS SOON AS POSSIBLE TO ALLOW TRANSITION

To avoid potential gap in certification between MDD and MDR we recommend you to apply for MDR 2017/745 as soon as you are ready. Please read Team NB statement on this link.

ARE YOU READY FOR BREXIT?

- More MHRA guidance on procedural aspects of the post-Brexit system of regulation is expected.
- MHRA is in negotiations with several EU notified bodies wanting to become designated UK approved bodies, to be able to apply the UKCA and UKNI marks. The three remaining UK-based notified bodies will automatically become UK approved bodies on 1 January.
- The UK's new MedTech products registration system has been developed and tested successfully.
- The UK system will be open for use on a voluntary basis on 1 January 2021.
- European commission published a Brexit readiness checklist. Follow this link and make sure you are ready for 1st Jan 2021.
- See below matrix where we clarify the requirements for the UK Market.

	Selling in England, Wales & Scotland	Selling in Northern Ireland	Selling in EU
GB-based Manufacturer with EU NB	**From January 2021** All devices need to be registered with MHRA according to the grace period. **Before July 2023** Update documentation and labelling to affix UKCA mark.	**Before January 2021** Assign EU-Authorised Representative. **From January 2021** All devices need to be registered with MHRA according to the grace period. Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline.	**Before January 2021** Assign EU-Authorised Representative. **From January 2021** Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline.
EU-based Manufacturer with EU NB	**From January 2021** All devices need to be registered with MHRA according to the grace period. Assign UK RP unless a manufacturer based in NI. **Before July 2023** Update documentation and labelling to affix UKCA mark.	**Before January 2021** Assign UK RP unless a manufacturer based in NI. **From January 2021** All devices need to be registered with MHRA according to the grace period. Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline	**From January 2021** Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline.
Non-UK/EU-based Manufacturer with EU NB	**From January 2021** All devices need to be registered with MHRA according to the grace period. Assign UK RP unless EU Authorized Representative is based in NI. **Before July 2023** Update documentation and labelling to affix UKCA mark.	**Before January 2021** Assign UK RP unless EU-Authorised Representative based in NI. **From January 2021** All devices need to be registered with MHRA according to the grace period. Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline	**From January 2021** Update documentation and labelling to affix CE mark according to the MDR and IVDR timeline.

SOME WORDS FROM OUR HEAD OF NOTIFIED BODY

2020 has certainly been a challenge and when the year is coming to an end I usually reflect over the past year.

During the year we all have learned a new word Covid-19, a virus which has challenged us both privately and professionally. I think it is important that all people involved in the medical device industry take pride in that we have all done everything within our power to make the world ever better.

Intertek Medical Notified Body reached a milestone this year when we got designated for MDR 2017/745. We have already completed the first TD assessments and Audits and see a strong demand for this service in 2021. As we have previously communicated, as soon as you are ready with your application please contact us via this link.

We have a very clear purpose to make the world a better, safer and more sustainable place for all. In these times - now more than ever – we are performing a truly mission-critical role in society to ensure that the highest quality, safety and sustainability standards are maintained in global supply chains. I am so proud of the way our colleagues and you as client have brought all your effort to your work every day.

Looking ahead into 2021 the challenge will remain, but I am convinced that we together will contribute to make sure our communities, and indeed the whole world gets through these different times in the safest possible way.

Finally, I would like to, on behalf of the organisation wish you a very happy holiday season and send you all our good wishes for 2021.

Best Regards

Curtis Riley, Head of Notified Body