# NEWSLETTER December 2019

***Brussels, 26.09.2019***

## Summary of safety and clinical performance - A guide for manufacturers and notified bodies

*"These Guidelines describe the methodology The Regulation (EU) 2017/745 requires that the manufacturer shall draw up a SSCP for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices."*

Read more:
https://ec.europa.eu/docsroom/documents/37323/attachments/1/translations/en/renditions/native

***Brussels, October 2019***

## Good news for *legacy devices* – the European MDCG weighs in

*"Certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC will remain valid until 27 May 2024 at the latest, but only under specific conditions…"*

Read more:
https://ec.europa.eu/docsroom/documents/37402/attachments/1/translations/en/renditions/native

***Brussels, October 2019***

## Questions and answers on requirements for notified bodies

*"The medical Device Coordination Group sheds some light on the requirements that must met by the NBs regarding Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)*

Read more:
https://ec.europa.eu/docsroom/documents/37688/attachments/1/translations/en/renditions/native

***Brussels, November 2019***


## European Commission extends application deadline for MDR, IVDR expert panels to late November 2019

*"Since the number of applicants to serve on the panels (divided in 11 subject areas relating to high-risk medical devices and IVDs) has reportedly been lower than anticipated, the EC hopes to attract a greater number of qualified individuals by extending the application deadline…"*

Read more:
https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en

***Brussels, 25.11.2019***

## MDR second Corrigendum - extended grace period for some self-certified Class I medical devices

"*A class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, ..., may be placed on the market or put into service until 26 May 2024..*"

Read more:
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

***London, 12.12.2019***

## The Conservative Party won the UK's election with the slogan "*Get Brexit done*" – what does that mean for MD and IVD Industries?

*"Most likely the UK will leave the EU on January 31st, 2020. There will be time to negotiate a trade deal until December 31st, 2020, which can be extended by a maximum of two years. Boris Johnson insists he can get this new deal done in 11 months. But until that agreement is reached, a no-deal Brexit is still on the table.*
*For the medical device and IVD industries, questions regarding applicability of the MDR and IVDR in the UK, Notified Body partnerships, European versus UK in-country representation and related issues remain uncertain"*

***Brussels, December 2019***

## MDCG - new guidance on sampling of MDR Class IIa/ IIb and IVDR Class B/C devices for the assessment of the technical documentation

*"This guidance defines the requirements of sampling for Class IIa and Class IIb devices under the MDR and Class B and Class C devices under the IVDR for the of assessing the technical documentation. It also clarifies the tasks to be performed by the notified body including the applicability of Chapter II of Annex IX of both Regulations and the extent of the technical documentation assessment…"*

Read more:
https://ec.europa.eu/docsroom/documents/38669/attachments/1/translations/en/renditions/native

***Brussels, December 2019***

## MDCG released an explanatory note on MDR codes

*"These codes are primarily used by designating authorities to define the notified body scope of designation but they are also used by the notified body to:*
*1) describe the individual qualification of the NBs staff members*
*2) describe the qualification required for assessing a device"*

Read more:
https://ec.europa.eu/docsroom/documents/38670/attachments/1/translations/en/renditions/native

***Netherlands, December 2019***

## 3 dutch and 1 german Notified bodies obtained designation to issue CE Mark certifications under the MDR

*Now a total of 9 NBs is able to certify devices under the European Medical Devices Regulation and 3 for IVDR. It is estimated that the notified bodies designated under MDR so far cover "about half of existing certificates." The Commission expects that figure to climb as it aims to fulfil its target of 20 designations in the first quarter of 2020*

- *BSI (UK)*
- *TÜV SÜD (Germany)*
- *DEKRA (Germany)*
- *TÜV Rheinland (Germany)*
- *IMQ (Italy)*
- *BSI NL (The Netherlands)*
- *Dare!! ( The Netherlands)*
- *DEKRA Certification B.V. (The Netherlands)*
- *MedCert (Germany)*

***We will be there, come and meet us!***


20-22 January 2020
Sao Paulo (Brazil)
Exhibition booth with three persons

*Chemsafe wishes you happy Holidays and a Happy New Year!*