Brussels, October 2020

Actor Registration Request Process for Economic Operators

The European Commission released two infographics that explain the process of obtaining the SRN (single registration number) via EUDAMED

Read more:
https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_actor_registration_request_process_en.pdf

Brussels, 11th November 2020

The EU Commission has released a proposal on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

"Its scope is to prepare for and manage the impact of major events on medicinal products for human use and of public health emergencies on medicinal products and on medical devices;
monitor and report on shortages of medicinal products and medical devices;
provide advice on medicinal products with the potential to address public health emergencies;
provide support for the expert panels designated in accordance with Implementing Decision (EU) 2019/1396."

Read more:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0725&from=EN

Brussels, 28th November 2020

The EU commission released recommendations on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection

"This Recommendation sets out guidance for Member States regarding the use of rapid antigen tests to detect SARSCoV-2 infection, it recommends Member States to conduct rapid antigen tests in addition to RT-PCR tests in clearly defined settings and with the aim to contain the spread of the coronavirus, to detect SARS-CoV-2 infections and to limit isolation and quarantine measures."

Read more:
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020H1743&from=EN

Brussels, November 2020

MDCG Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746

"This guidance, relating to the application of Regulation (EU) 2017/746 addresses the classification of IVDs and provides clarifications on the classification rules as set out under Annex VIII. The primary purpose of this document is to provide guidance to manufacturers, notified bodies and health institutions on how to classify an IVD prior to placing it on the market"

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_guidance_classification_ivd-md_en.pdf

November 2020

One new NB can certify devices under the European Medical Devices Regulation, bringing the total to 18.

- *UDEM Adriatic d.o.o. (Croatia)*

Also for the IVDR there has been e new designation, bringing the total to 5.

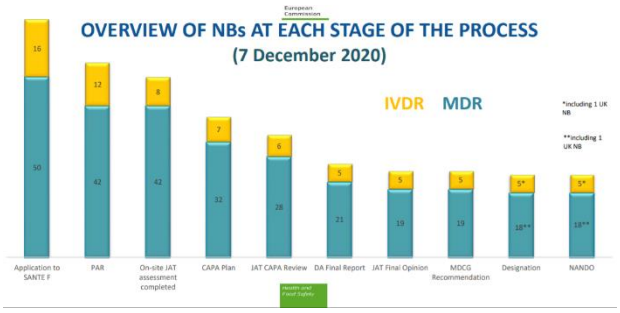
- *TÜV Rheinland GmbH (Germany)*

Brussels, 4th December

CAMD position paper concerning the verification of actors according to article 31 of the MDR for the provision of EUDAMED Actors' module

The position paper offers clarifications regarding the registration of the operators concerned by this module by providing a list of elements needed by Competent Authorities for verification before issuing SRN

Read more:
https://www.camd-europe.eu/wp-content/uploads/2020/12/CAMD-Position-Paper-ACT-verification-in-Eudamed.pdf



December 2020

The European Commission released an overview on NB designation situation

The European Commission has released this overview of the Notified Bodies at each stage of their application process for the upcoming MDR and IVDR. The vast majority of NBs are at the initial steps, which has an important impact on the timeline of your submissions.

Read more:
https://ec.europa.eu/health/sites/health/files/md_newregulations/docs/notifiedbodies_overview_en.pdf

December 2020

The UKs Government provided a guidance on how to register medical devices to place on the market

Starting January 2021, the following devices in Great Britain will need to be registered with the MHRA under existing arrangements:

- *Class I medical devices*
- *IVDs*
- *custom-made devices*

All other classes of device placed on the market will require registration with the MHRA subject to grace periods over the following 12 months, depending on the class of devices.
In Great Britain devices must conform to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) so that they can be registered with the MHRA.

Read more:
https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market-from-1-january-2021

December 2020

The European Commission released a Eudamed FAQ document on the Actor Modul

This document provides answers regarding the following topics:
1.Countries available in EUDAMED from December 2020
2. Actor registration process
3. SRN
4. Actor roles
5. EUDAMED users
6. Support
7. Data Exchange.

Read more:
https://ec.europa.eu/health/sites/health/files/md_eudamed/docs/md_actor_module_q-a_en.pdf

December 2020

The MDCG provided a Q&A on how to perform medical device notified body audits during COVID-19 pandemic

The issues covered by this document have been identified in the context of the implementation of the principles outlined in the guidance document "MDCG 2020-4 Guidance on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions"
To ensure medical care and to prevent the shortages of products on the market, initial certification audits under the Directives may be performed using the principles and guidance outlined in MDCG 2020-4. This also requires the notified body to perform a case-by-case assessment.

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2020-17-guidance-mdcg-qa_en.pdf

December 2020

MDCG Position Paper on UDI assignment for Spectacle lenses & Ready readers

This document should be read in conjunction with the relevant provisions of the MDR (notably Chapter III and Annex VI) and related UDI guidance documents. Annex I & II of this document outline the Basic-UDI-DI and UDI-DI groupings to be assigned by manufacturers of spectacle lenses and ready readers.

Read more:
https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_18_en.pdf

December 2020

How does SCIP impact Medical Devices?

The SCIP database provides information on substances of Concern In articles as such, or in complex objects (Products) established under the Waste Framework Directive.
As of January 5th, 2021, companies supplying articles containing substances of very high concern (SVHCs) on the Candidate List in a concentration above 0.1% (w/w) to the EU market have to submit information on these articles to ECHA.
Anything that can be assimilated to the REACH definition of "article" falls within the SCIP scope: even packaging (Q&A 1662) and medical devices (Q&A 1663)

Chemsafe wishes you happy Holidays and a Happy New Year!