--- EN --- [European Commission] MDCG 20022-21 Position Paper on PERIODIC SAFETY UPDATE REPORT (PSUR) according to Regulation (EU) 2017/745 (MDR) published.

Manufacturers of Class IIa, IIb, and III devices are required to establish a PSUR to allow for a more consistent, standardized, and systematic review of all Postmarket Surveillance (PMS) data. This guidance helps manufacturers to meet the requirements of the Article 86 of Regulation 2017/745 on Medical Device (MDR).

--- FR --- [Commission Européenne] Le MDCG 2022-21 sur le RAPPORT PÉRIODIQUE D'ACTUALISATION DE LA SÉCURITÉ conformément au Règlement 2017/745 a été publié.

Les fabricants de dispositifs de classe IIa, IIb et III sont tenus d'établir un PSUR pour permettre l'examen plus cohérent, normalisé et systématique de toutes les données de Surveillance Après Commercialisation (SAC). Ainsi ce guide fournit une aide aux fabricants afin qu'ils répondent aux exigences de l'article 86 du règlement 2017/745 sur les dispositifs médicaux (MDR).

#MedicalDevices#RegulatoryAffairs#MDCG#EuropeanComission#MDR#CEmarking#PSUR

Medical Devices
Medical Device Coordination Group Document MDCG 2022-21

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GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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