Communication from the Commission:
Guidelines on the adoption of Union-wide derogations for medical devices

On 19 May 2020, the Commission published Guidelines on the adoption of Union-wide derogations for medical devices. Article 59 of Medical Devices Regulation (EU) 2017/745 sets out rules on the adoption of national derogations and of Union-wide derogations for medical devices.

Union-wide derogations should be regarded as a measure of last resort, only to be considered by the Commission in exceptional cases to ensure patient health or safety or to protect public health.

The Guidelines provide information on the adoption of those Union-wide derogations, in particular the criteria that the Commission will take into account to determine whether the extension to the territory of the Union of a national derogation is necessary and justified for a medical device.

The document also provides information on the adoption process, including the role of Member States, and the general conditions that the Commission should set for Union-wide derogations by means of implementing acts.