State of play of Joint implementation Plan on actions considered necessary to ensure the sound functioning of the new framework for medical devices under the MDR (02/07/2020)

N°	**Priority actions by May 2020**	**Legal basis**	**Justification for updating of tasks and/or deadline**	**Deadline**
1	**EUDAMED** - Make available the actor registration module.		Actors registration module deployment and use postponed, but development continues as planned. Possibility to make it available separately or the first 3 modules together: 1) actors registration, 2) devices registration including UDI, 3) certificates.	Postponed to Q4 2020 for actors registration module, including SRN. By Q2 2021 for the devices and certificates modules
	- Provide regular updates on the development of EUDAMED.	Art 123 3) d)	To share EUDAMED development plan and provide visibility on next steps.	On a regular basis in the MDCG Subgroup on EUDAMED
	- EUDAMED guidance 1. Guidance on administrative and technical solutions in the absence of EUDAMED.		1. Document still required since Eudamed planned to be fully available by May 2022 and new DoA by May 2021.	1. Endorsement by Q3 2020
	2. Position paper on the use of the actor registration module in Member States.		2. Document still required in line with the decision of the MDCG on 11. March 2020.	2. Endorsement by Q3 2020

	- Establishing an MDCG subgroup on EUDAMED.		Facilitate coordination and interaction policy and IT.	Established in Q2 2020 (first meeting on 25/6/2020) Selection of observers to be finalised in Q3

2	**Clinical evaluation** 2 guidance documents 1. on equivalence. 2. on clinical evidence needed for legacy medical devices.	Art 61 and Annex XIV	1. To provide guidance on the demonstration of equivalence, based on data pertaining to an already existing device on the market, for the purpose of CE-marking under the MDR. 2. To provide guidance for manufacturers and notified bodies to prepare for conformity assessment according to the MDR of medical devices currently certified under the directives.	1. Published in April 2020 2. Published in April 2020
3	**Transitional provisions** 3 guidance documents 1. on interpretation / implementation of "significant changes" in accordance with Art 120(3) of the MDR. 2. on transitional provisions for consultations of authorities on devices containing ancillary medicinal products and on devices manufactured using TSE susceptible animal tissues.	Art 120 (2) and 3)		1. Endorsed on 12/03/2020 2. Endorsed on 10/06/2020

	3. on how affected manufacturers of some class I devices can make efficient use of the transitional provisions.	Art 120(3) and (4)		3. Endorsed on 12/3/2020; requires minor updating to reflect new DoA
4	**Monitoring of devices availability and measures to prevent or remedy shortages** 1. Request regular reporting by industry and notified bodies and monitor market developments and activities performed by notified bodies aiming at detecting possible delays that could bring to shortage of devices on the market. 2. Examine different means for taking measures to ensure availability of safe and critical medical devices and provide guidance, as appropriate. 3. Provide for mechanisms to communicate between National Competent Authorities and the Commission on availability, potential risk of shortages and		1. 1 year extension of deadline for renewal of MDD certificates but several months of NB activities potentially lost in 2020 due to Covid 19 crisis. To monitor specifically certificates which will expire in 2020 and 2021 2. Specific actions related to COVID-19: - COM Recommendation on conformity assessment and market surveillance - COM guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context	Request for bi-weekly reporting from notified bodies as soon as the covid-19 situation allows Published on 16/03/2020 Published on 03/04/2020

	measures taken to ensure availability of safe and critical medical devices.		- European standards for certain medical devices and personal protective equipment.	Published on 25/03/2020
			- MDCG guidance on remote audits	Published on 08/04/2020
			- CIRCA BC notification system of national derogations related COVID-19	Available from 25 March 2020
			- MDCG guidance on regulatory requirements for ventilators and related accessories	Published on 24 April 2020

5	**Expert panels** - Appoint experts to panels and publish the lists of appointed experts along with their CVs and declarations. - Publish the names of experts included on central list of available experts. - Establish expert panels for Clinical Evaluation Consultation Procedure (CECP) / Performance Evaluation Consultation Procedure (PECP).	Art 106	1. Consultation of MDCG on selected experts. 2. Appointment of experts 3. Website on expert panels 4. Make available the panels	1. Finalised 2. By end July 2020 3. Finalised 4. By Q4 2020
6	**Transparency** - Issue a fact sheet on information to become publicly accessible when EUDAMED is in place.	Art 33	Document needed by Member States when MDR becomes applicable.	Finalised July 2020
7	**Reprocessing single use devices** - Common specifications through Implementing Act.	Art 17(5)	In light of MDR application date postponement, IA can only be applicable for May 2021, but should be adopted asap to facilitate for MS to adopt national rules.	By Q3 2020

8	**Standardisation** 1. Standardisation Request to CEN /CENELEC to review or update the existing harmonised standards on medical devices and to draft new standards in support of the MDR/IVDR through Implementing Decision. 2. Publication in the OJ of lists of references of harmonised standards in support of the MDR/IVDR through Implementing Decisions.	Art 8(1)	Legal basis as per the Standardisation Regulation (EU) 1025/2012 for harmonised standards and the publication of their references in the OJ. Harmonised standards conferring presumption of conformity to facilitate the conformity assessment of devices and their certification.	Adopted on 15 May, rejected by CEN/CENELEC on 16 June. New procedure to be launched for possible adoption from Q1 2021 From Q1 2021 (depending on a new Standardisation Request)