Anhang 1 – Proposed measures for a revision of Regulation (EU) 2017/745 on medical devices

Overview of the proposed measures

	Demand	Solution / how it can be achieved	Justification	Problem description	Current requirement
1	Remove the limited validity of certificates currently stipulated by law	Amendment to Art. 56 (2) MDR: “The certificates shall be valid for the ~~period they indicate, which shall not exceed five years~~ lifetime of the device, subject to the manufacturer’s post-market surveillance system supporting the quality, safety and performance over the lifetime of the device in accordance with Chapter VII, Section 1 and Part B of Annex XIV. ~~On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures.~~ Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.”	Certificates issued as part of certification according to the MDR or IVDR should have an indefinite validity. Manufacturers' quality management systems are regularly monitored and audited. Furthermore, the MDR and IVDR require the creation and regular updating of reports and documents (PMS report, PSUR, SSCP, CER, QMS, RMS, trend report, vigilance reports, etc.), which are also regularly reviewed as part of the lifecycle approach. Substantial changes to medical devices and in vitro diagnostics are evaluated when the technical documentation is updated. This ensures continuous monitoring of manufacturers by Notified Bodies. Continuous validity of the certificates, provided the manufacturer fulfils the requirements specified in MDR and IVDR, can avoid gaps in supply in the event that the new certificate cannot be issued in time before its validity date	A complete recertification of all processes and documents every five years, in addition to the mentioned measures and reviews, does not provide added value in terms of ensuring or increasing patient safety and product quality but leads to unnecessary and avoidable personnel and financial burdens.	Art. 56 (2) MDR: “The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.“

			expires through no fault of the manufacturer.		
2	Establishment of binding deadlines for the conformity assessment procedures	Amendment of Annex VII Section 4.5.1 MDR: “The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields. The notified body shall confirm completeness or reject an application for conformity assessment within 10 days as of the date of application. If the notified body decides that the application is complete this is deemed to constitute an offer of a contract that may be accepted by the manufacturer. The notified body shall ensure that the procedure for conformity assessment is completed within a maximum of 180 days after the submission of a valid application, excluding consultation with competent authorities as part of the conformity assessment procedure. A clock stop is foreseen.”	To define a binding overall timeframe for the assessment procedure is the only way to give manufacturers the essential planning certainty they need in order to market products. This planning certainty is existential and urgently needed to secure Germany and the EU as a business location. Any deviations (e.g. for necessary processing of non-conformities) for from the schedule can be made after consultation with and approval by the manufacturer. A clock stop is foreseen during which the evaluation of a medical device is officially stopped, while the applicant prepares responses to questions from the Notified Body. The clock resumes when the applicant has sent its responses.	Currently, there are significant delays in procedures, making it nearly impossible for manufacturers to plan the review of technical documentation and the overall completion of the conformity assessment and certification. Additionally, timelines for conformity assessment differ greatly between Notified Bodies.	Annex VII Section 4.5.1 MDR: “The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.”

3	Establishment of binding deadlines for the assessment of major changes to the quality management system	Amendment to Annex IX Chapter II Nr. 2.4 MDR: “The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall within 90 days assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.”	To define a binding timeframe for the assessment major changes to the quality management system is the only way to give manufacturers the essential planning certainty they need.	Currently, there are significant delays in assessing major changes to the quality management system, making it nearly impossible for manufacturers to plan. Additionally, timelines for assessment of major changes differ greatly between Notified Bodies.	Annex IX Chapter II Nr. 2.4 MDR: “The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.”
4	Establishment of binding deadlines for the assessment of major changes	Amendment to Annex IX Chapter II Nr. 4.10 MDR: “4.10. Changes to the approved device shall require approval from the notified body which issued the	To define a binding timeframe for the assessment major changes to the approved device is the only way to give manufacturers the	Currently, there are significant delays in assessing major changes to the approved device, making it nearly	Amendment to Annex IX Chapter II Nr. 4.10 MDR: “4.10. Changes to the approved device shall require approval from the notified body which issued the EU

	to the approved device	EU technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall within 90 days assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.“	essential planning certainty they need.	impossible for manufacturers to plan. Additionally, timelines for assessment of major changes differ greatly between Notified Bodies. Some Notified Bodies take approximately 1,5 years.	technical documentation assessment certificate where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above mentioned changes it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall within 60 days assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 52 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.“
5	Deadline extension for PSUR submission concerning class	Amendment to Art. 86 (1) 2nd paragraph MDR: “Manufacturers of class IIb and class III devices shall update the PSUR in case of significant	Updating PSURs without an apparent need, such as significant changes or serious incidents or a significant increase in known adverse reactions, does not increase the safety of	For class IIb and class III devices the PSUR must be updated at least annually, even for long established	Art. 86 (1) 2nd paragraph MDR: “Manufacturers of class IIb and class III devices shall update the PSUR at least annually. That PSUR shall, except in the case of custom-made

	IIb and class III devices	changes in the conclusions of the benefit-risk determination or in the main findings of the PMCF compared to the date of the initial CE certificate for the device concerned or compared to the last PSUR update, at least ~~annually~~ every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III."	the products. On the contrary, too many resources are tied up and these are then lacking in key areas.	existing products or when no substantial changes have occurred. This leads to considerable time and unnecessary costs for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system without adding to patient safety.	devices, be part of the technical documentation as specified in Annexes II and III."
6	Deadline extension for PSUR submission concerning class IIa devices	Amendment to Art. 86 (1) 3rd paragraph MDR: "Manufacturers of class IIa devices shall update the PSUR when necessary and at least every ~~two~~ four years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III."	Updating PSURs without an apparent need, such as significant changes or serious incidents or a significant increase in known adverse reactions, does not increase the safety of the products. On the contrary, too many resources are tied up and these are then lacking in key areas.	For class IIa devices the PSUR must be updated at least every two years, even for long established existing products or when no substantial changes have occurred. This leads to considerable time and unnecessary costs for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system	Art. 86 (1) 3rd paragraph MDR: "Manufacturers of class IIa devices shall update the PSUR when necessary and at least every two years. That PSUR shall, except in the case of custom-made devices, be part of the technical documentation as specified in Annexes II and III."

				without adding to patient safety.	
7	Deadline extension for PSUR submission concerning devices which have had no serious incident in the last year	Amendment to Art. 86 (1) 4th paragraph: "Manufacturers of devices that have had no serious incident in the last year shall update the PSUR when necessary and at least every five years. For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII."	This paragraph would address long established existing products.	This provision leads to considerable time and unnecessary costs for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system without adding to patient safety.	Art. 86 (1) 4th paragraph MDR: "For custom-made devices, the PSUR shall be part of the documentation referred to in Section 2 of Annex XIII."
8	Deadline extension for SSCP submission	Amendment to Art. 61 (11) 2nd paragraph MDR: "For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least ~~annually~~ every two years with such data."		For class III devices the SSCP must be updated at least annually, even for long established existing products or when no substantial changes have occurred. This leads to considerable time and unnecessary costs for both manufacturers and Notified Bodies. These costs ultimately have to be covered by the healthcare system	Art. 61 (11) 2nd paragraph MDR: "For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data."

				without adding to patient safety.	
9	Exemption for special products for the requirement to establish a SSCP	Amendment to Art. 32 (1) with addition of 2nd paragraph MDR: “For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors”.	These listed products are already exempted from implant card requirements, from the requirement to perform clinical investigations pursuant to Art. 61 (4) MDR.	As they are implantable, they are subject to SSCP requirements, which represent a high burden without increasing safety.	Art. 32 (1) MDR: “For implantable devices and for class III devices, other than custom-made or investigational devices, the manufacturer shall draw up a summary of safety and clinical performance.”
10	Clarification of the timeline of Article 70 (7) MDR	Amendment to Art. 70 (7) MDR: “(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State	This paragraph is interpreted very differently by the Member States. This should help to obtain authorization more quickly, as Member States are prohibited from defining their own interpretation of the times specified in the MDR.		Art. 70 (7) MDR: “(b) in the case of investigational devices, other than those referred to in point (a), as soon as the Member State concerned has notified the sponsor of its authorisation, and provided that a negative opinion which is valid for the entire Member State, under national law, has not been issued by an ethics committee in the Member State concerned in respect of the clinical investigation. The Member State shall notify the sponsor of the authorisation within 45

		shall notify the sponsor of the final authorisation within 45 days of the validation date referred to in paragraph 5. During the validation, the period of time is officially stopped while the applicant prepares responses to questions from the Member State («clock stop»). The Member State may extend this period by a maximum of further 20 days for the purpose of consulting with experts."			days of the validation date referred to in paragraph 5. The Member State may extend this period by a further 20 days for the purpose of consulting with experts."
11	Definition of the terms "if indicated" in Art. 61 (11) 2nd paragraph MDR	The definition of the terms "if indicated" in Art. 61 (11) 2nd paragraph MDR could be published in the MDCG Guidance 2019-9.	The terms "if indicated" are not define and thus unclear. An interpretation is required with e.g. examples.	Notified Bodies generally automatically expect annual updates. That is not the intention of the European legislator.	Art. 61 (11) 2nd paragraph MDR: "For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in Article 32 shall be updated at least annually with such data."
12	Revision of MDCG 2023-7	Amendment of footnote 7 on page 6 MDCG 2023-7: "7 "Clinical data" includes data from any of the sources listed in the Article 2(48) definition. This includes data from "a device for which equivalence to the device in question can be demonstrated". The definition include clinical data of well-established relevant similar devices but does not include a requirement for a contract	This would permit to make the procedure analogous to MDR conversions, where data from relevant similar devices can also be used for well-established technologies, which is then confirmed by PMCF.	There is an absurdity to have an exemption from the obligation to conduct studies, but to still have to conduct studies with the product itself for 'sufficient clinical data', which renders the article useless for all products	Page 6 Footnote 7 MDCG 2023-7: "7 "Clinical data" includes data from any of the sources listed in the Article 2(48) definition. This includes data from "a device for which equivalence to the device in question can be demonstrated". The definition does not include a requirement for a contract between the manufacturers. Additional note: MedDev 2.12/2 indicated that PMCF studies should be undertaken for devices when the

		between the manufacturers. Additional note: MedDev 2.12/2 indicated that PMCF studies should be undertaken for devices when the clinical evaluation was based on equivalence. In some cases, execution of such studies may have been a condition of certification under the Directives. The acceptance of clinical evidence from EDs as part of the clinical evidence package to support MDR certification does not invalidate any such conditions of certification."		mentioned (without CS).	clinical evaluation was based on equivalence. In some cases, execution of such studies may have been a condition of certification under the Directives. The acceptance of clinical evidence from EDs as part of the clinical evidence package to support MDR certification does not invalidate any such conditions of certification."
13	Determination of clear costs	Amendment of Art. 50 MDR: "Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out ~~and shall make those lists publicly available~~. Notified bodies shall track the average duration of conformity assessment by risk class and type of procedure and provide these to the Commission in a format to be determined by the Commission. The Commission will publish the standard fees and average duration of conformity assessment procedures of notified bodies to the general public in a standardized Union dashboard on its website. The dashboard shall	To have planning certainty and transparency it is essential for manufacturers to reliably assess the costs and duration of a conformity assessment and certification before commencing it. Therefore, Notified Bodies should be obliged to provide a binding offer regarding costs and scope of services, including a complete listing of work steps. It must also be possible for manufacturers to compare costs for similar services. This contributes to the reliable application of the MDR and IVDR.	Currently, the costs associated with conformity assessment procedures are unpredictable at the beginning of the process.	Art. 50 MDR: "Notified bodies shall establish lists of their standard fees for the conformity assessment activities that they carry out and shall make those lists publicly available."

		publish comparative metrics for fees of notified body activities, enabling manufacturers to make an informed choice of notified body based on risk class and type of the device.”			
14	Financial support of SMEs	Insertion of Art. 50c MDR: “Fee deferral, fee reduction and fee exemption 1. The payment of the following fees shall be deferred until the notification of the final decision on the conformity assessment is issued, or the application is withdrawn: (a) the fee for an application for conformity assessment of a device, as referred to in article 52 of this Regulation, including application of the procedures set out in section 5 of Annex IX or section 6 Annex X of this Regulation; (b) the fee for quality system audit undertaken for the purpose of conformity assessment application of a device, as referred to in section 2.3 of Annex IX of this Regulation and Annex 6.3 of Annex XI of this Regulation.	Under the MDR, there are significant cost increases, disproportionately burdensome to SMEs. Therefore, the aim must be to reduce costs to avoid product discontinuations and business closures, particularly among SMEs.		

		2. The fees referred to in paragraph 1 shall be payable within 45 days of the date of the notification of the final decision on the conformity assessment application, or within 45 days of the date of the notification of withdrawal of the application. 3. The following fees shall be reduced for SMEs: (a) Administrative charges (including but not limited to application fees, administrative fees relating to changes, annual certificate maintenance fees, travel time charges and administrative fees relating to handling of external services) (b) Audit and unannounced audit fees; (c) Product testing by the notified body; (d) Documentation review (including but not limited to technical documentation assessment, clinical evaluation report assessment, expert panel or other third party consultation, summary of safety and clinical performance validation, PSUR			

		evaluation, assessment of changes); (e) Reporting. 4. SMEs shall be exempted from the following fees: (a) The opinions of expert panels provided on the basis of article 61 (2) and pursuant to section 5.1 of Annex IX of this Regulation and sections 5 of Annex IX or section 6 of Annex X shall be provided free of charge. (b) Consultation with medicinal product authorities, consultation with human tissue and cells competent authority and consultation with the coordinating competent authority for devices utilizing animal tissues.”			
15	Definition of the SME	Insertion of Art. 50a MDR: “SME status 1. This Regulation establishes the circumstances in which, by derogation from the relevant provisions of a written agreement with a notified body, fees due to a competent authority, SMEs may pay reduced fees, defer payment of fees, forego fees payment or receive administrative assistance	If new provisions are foreseen in the MDR to support SMEs it is necessary to define an SME.		

		when preparing and submitting applications for conformity assessment under Regulation (EU) No 2017/745 to a notified body designated in accordance with article 42 of Regulation (EU) No 2017/745 and when applying to an expert panel designated in accordance with article 106 of Regulation (EU) No 2017/745 or a Union Member State. 2. The benefits set out in Article 50a (1) and in Article 50d (2) shall apply to SMEs within the meaning of Recommendation 2003/361/EC in the version of 6 May 2003 which are established in the Community. 3. Unless otherwise specified by implementing act by the Commission pursuant to the procedure set out in Article 114 (3) of this Regulation, the SME benefits shall apply to applications concerning medical devices, accessories and devices in the meaning of Annex XVI respectively."			
16	Office for SMEs and mid-caps	Insertion of Art. 50d MDR: "Office for SMEs and mid-caps 1. The Commission shall set up dedicated administrative structures and specific procedures	It would be appropriate to create an Office to offer administrative assistance to SMEs and mid-caps.	SMEs and mid-caps lack of capacity and also of experience with conformity assessment and the notified bodies. This	

		for the establishment of an Office for SMEs and mid-caps. 2. The Office for SMEs and mid-caps shall have the following tasks: (a) to give advice to applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation (EU) No 2017/745; (b) to ensure the appropriate monitoring of all requests and applications submitted by the same applicant and related to a particular medical device; (c) to organise workshops and training sessions for applicants on the administrative and procedural steps necessary to comply with the requirements laid down in Regulation (EU) No 2017/745."		impairs the development and marketing of new medical devices.	
17	Definition of the mid-cap	Insertion of Art. 50b MDR: "Mid-cap status The benefits set out in Article 50d (2) shall apply to middle-capitalisation firms (or mid-caps) within the meaning of the Communication C/2021/8712 from the European Commission on the Guidelines on State aid to promote	If new provisions are foreseen in the MDR to support mid-caps it is necessary to define a mid-cap.		

		risk finance investments in the version of 16 December 2021."			
18	Avoidance of redundancy in documentation	Establishment of one core document to list fundamental information that is currently repeated in various documents, which is then used during the assessment by the Notified Body. This document should be used before EUDAMED is fully functional.	Unnecessary bureaucratic effort should be reduced so that both manufacturers of medical devices and IVDs as well as Notified Bodies can pursue a more efficient and "benefit-risk-based" approach in the conformity assessment process, while maintaining a high standard in assessing safety and performance aspects.	In the context of necessary market surveillance from the industry's perspective (Post-Market Surveillance), fundamental product information (e.g., sales figures, number of incidents) is redundantly requested across a variety of documents (e.g., PMS plan, PSUR, PMCFP/PMPFP, PMCFE/PMPFE, CEP/PEP, CER/PER). This leads to considerable time and unnecessary costs for both manufacturers and Notified Bodies.	
19	Amendment to classification rule 19	Amendment to Annex VIII Rule 19 MDR as follows: "Rule 19	The risk of the use of nanomaterials shall be taken into account in the risk assessment process. However, too many products with no serious concern for health may fall under this rule. Some of these products have	The European Parliament has already reduced the up-classification in Class III only when the use of nanomaterials is	Annex VIII Rule 19 MDR: "Rule 19

		All devices incorporating or consisting of nanomaterial are classified as: class IIb if they present a high or medium potential for internal exposure; class IIa if they present a low potential for internal exposure; and class I if they present a negligible potential for internal exposure.”	been distributed without incidents for years.	intentional and part of the intended use of the product (amendments 2 and 304), but this is not sufficient. In his justification, the Parliament stated that “many medical devices contain nanomaterials, but do not pose any danger to the patient.”	All devices incorporating or consisting of nanomaterial are classified as: — class III if they present a high or medium potential for internal exposure; — class IIb if they present a low potential for internal exposure; and — class IIa if they present a negligible potential for internal exposure.”
20	Amendment to classification rule 14	Amendment to Annex VIII Rule 14 MDR as follows: “Rule 14 All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices and where such substance has an impact on the intended purpose of	According to Recital (59) MDR for invasive devices “The classification rules should take into account the place where the device performs its action in or on the human body.” This should also apply in a risk-based manner for implantable devices that are placed in teeth even if they might contain such a substance they are not high-risk products. In chemical products such as dental cements substances react and are no longer available in their original form after the reaction. Therefore, it does not matter if - if used on their own they might be considered as a	Many dental filling materials contain such substances and would have to be classified as class III. This would require a disproportionate amount of resources for both manufacturers and notified bodies and is in no way justifiable with regard to relatively low-risk products.	Annex VIII Rule 14 MDR: “All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive, and that has an action ancillary to that of the devices, are classified as class III.”

		the device, are classified as class III.”	medicinal product. In the conformity assessment the Medical Device should be in the focus, not components that are reacting. Alternatively, include an additional rule that in case dental products include [...] such product is classified as IIa following a risk based approach.		
21	Amendment to classification rule 11	Amendment to Annex VIII Rule 11 MDR: “Software intended for healthcare professionals to provide information which is used to take decisions with diagnosis or therapeutic purposes, is classified as class IIa, except if such decisions have an impact that may cause: death or an irreversible deterioration of a person's state of health, in which case it is in class III; or a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.	Rule 11 of the MDR states that software that provides information that is used to make decisions for diagnostic or therapeutic purposes must be classified in at least Class IIa. This broad formulation means that even applications with a low risk potential are classified in higher risk classes. Many DiGAs are currently legally classified in Class I. However, efforts are currently being made by the authorities to classify the products higher. To date, there are no indications in the databases of the regulatory authorities that these products pose an increased health risk. DiGAs are also subject to special clinical monitoring. This	While this specific rule aims to increase the patient safety of MDSW, it has also led to a tendency to classify almost all software with diagnostic or therapeutic functions as Class IIa or higher. This development and the resulting often erroneous interpretation leads to over-regulation, which inhibits innovation and makes access to useful digital health applications more difficult. This	Annex VIII Rule 11 MDR: “Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause: death or an irreversible deterioration of a person's state of health, in which case it is in class III; or a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb. Software intended to monitor physiological processes is classified as class IIa, except if it is intended for

		Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as Class I, unless the information provided has an impact that may cause: the death or irreversible deterioration of a person's state of health, in which case it is classified as class III, or a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb, or other health impairments requiring a intervention by healthcare professional, in which case it is classified as class IIa. The risk classification for software in general shall consider:	additional monitoring provides an additional safety net and enables potential risks to be identified promptly. No safety concerns have been signaled here either.	overregulation would have a particular impact on the nascent and highly innovative field of digital health applications (DiGAs).	monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.“

		The actual application context of the software The degree of autonomy of the software in decision-making."			
22	Amendment to classification rule 8	Amendment to Annex VIII Rule 8 MDR as follows: "Rule 8 All implantable devices and long-term surgically invasive devices which are intended to be placed in the teeth are classified as class IIa. All other implantable devices and long-term surgically invasive devices are classified as class IIb unless they: are intended to be placed in the teeth, in which case they are classified as class IIa; are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III;	The procedure of preparing teeth for placing materials in the teeth and the placing itself have already the biological effect of inducing the building of repair dentin. Therefore, every filling material used in vital teeth would have to be classified in class III if not exempted, as proposed.		Annex VIII Rule 8 MDR: "Rule 8 All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: are intended to be placed in the teeth, in which case they are classified as class IIa; are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth; are intended to administer medicinal products, in which case they are classified as class III;

		are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth; are intended to administer medicinal products, in which case they are classified as class III; are active implantable devices or their accessories, in which cases they are classified as class III; are breast implants or surgical meshes, in which cases they are classified as class III; are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.”			are active implantable devices or their accessories, in which cases they are classified as class III; are breast implants or surgical meshes, in which cases they are classified as class III; are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments.”
23	Clarification for accessories	Amendment to Art. 51 (1) MDR:	Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended		Art. 51 (1) MDR:

		"1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII. Legacy devices for which no serious incidents have occurred in the last 10 years are to be categorised in the same risk class under Regulation (EU) 2017/745 as under the Directive 90/385/EEC or the Directive 93/42/EEC."	purpose of the devices and their inherent risks. If the device has had no serious incident in the last 10 years, inherent risks can be excluded. The classification under the directives was sufficient. We suggest keeping this classification under the MDR.		"1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII."
24	Addition of absorbable implants in the list of exemptions from the obligation to have an implant card	Amendment to Art. 18 (3) MDR: "3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, ~~and~~ connectors and absorbable implantable devices. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom."	The implementation of an implant card is very burdensome. Beside the specifications and material costs, additional production and packaging processes must be installed which impact sterilization and transportation validations. There are many implantable devices which are made of an absorbable material. The absorption time depends on the material and lasts only for a few weeks or months. After the absorption is completed, the implant has gone, and the implant card must be discarded. In fact, the implant card is useful and beneficial for permanent implants. However, for absorbable products, the		Art. 18 (3) MDR: "3. The following implants shall be exempted from the obligations laid down in this Article: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors. The Commission is empowered to adopt delegated acts in accordance with Article 115 to amend this list by adding other types of implants to it or by removing implants therefrom."

			suitability and benefits should be reconsidered.		
25	Simplification for "Legacy devices" that have had no serious incidents in the last 10 years	Amendment to Art. 51 (1) MDR: "1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII. Legacy devices for which no serious incidents have occurred in the last 10 years are to be categorised in the same risk class under Regulation (EU) 2017/745 as under the Directive 90/385/EEC or the Directive 93/42/EEC."	Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. If the device has had no serious incident in the last 10 years, inherent risks can be excluded. The classification under the directives was sufficient. We suggest keeping this classification under the MDR.		Art. 51 (1) MDR: "1. Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII."
26	Change of language for the EU declaration of conformity	Amendment to Art. 19 (1) MDR: "1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be provided in English ~~translated into an official Union~~			Art. 19 (1) MDR: "1. The EU declaration of conformity shall state that the requirements specified in this Regulation have been fulfilled in relation to the device that is covered. The manufacturer shall continuously update the EU declaration of conformity. The EU declaration of conformity shall, as a minimum, contain the information set out in Annex IV and shall be translated into an official Union language or languages required by

		~~language or languages required by the Member State(s) in which the device is made available~~."			the Member State(s) in which the device is made available."
27	Change of language concerning devices intended for healthcare professional	Amendment to Art. 10 (11) MDR: "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. For devices made available to healthcare professionals, the device is accompanied by the information set out in Section 23 of Annex I in English. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."			Art. 10 (11) MDR: "Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient."
28	Establishment of a hierarchy between the requirements set by the MDR and by other overlapping or conflicting legislations	Amendment of Art. 1 MDR by adding a further paragraph: "The Commission is empowered to adopt delegated acts in accordance with Article 115 in order to amend Article 1 to determine hierarchy of specific requirements pursuant this Regulation in relation overlapping		Medical device manufacturers are confronted with the most diverse parallel requirements, as products that fall within the scope of the MDR can also fall within the scope of many other regulations. From a regulatory	

		or conflicting requirements in other Union legislation.”		perspective, implementation is often difficult and complex, especially for SMEs, as this overlap means that several product regulations may apply to a single product. In addition, the same concept is often defined differently in different regulations, which also makes it very difficult for medical device manufacturers to apply the numerous requirements.	
29	Expansion of the scope of application of electronic instructions for use (eIFU)	Deletion of Art. 1 3rd paragraph of the Commission implementing Regulation (EU) 2021/2226: “~~This Regulation does not cover products listed in Annex XVI to Regulation (EU) 2017/745.~~” Amendment to Art. 3 (1) of the Commission implementing Regulation (EU) 2021/2226:	For all medical devices, the provision of instructions for use in electronic form instead of in paper form can be beneficial. It can reduce the environmental burden and reduce costs for the medical device industry while maintaining or improving the level of safety. The possibility of providing instructions for use in electronic form instead of in paper form should not be limited to certain		Art. 1 3rd paragraph of the Commission implementing Regulation (EU) 2021/2226: “This Regulation does not cover products listed in Annex XVI to Regulation (EU) 2017/745.” Art. 3 (1) of the Commission implementing Regulation (EU) 2021/2226:

		"(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any ~~of the following~~ devices and their accessories covered by Regulation (EU) 2017/745.~~:~~ ~~(a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745;~~ ~~(b) fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745;~~ ~~(c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use.~~" Deletion of Art. 3 (2) of the Commission implementing Regulation (EU) 2021/2226: "~~(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions:~~	medical devices and accessories intended to be used under specific conditions. For reasons of safety and efficiency, users should always have the possibility to obtain those instructions for use in paper form upon request.		"(1) Manufacturers may provide instructions for use in electronic form instead of in paper form where those instructions relate to any of the following devices: (a) implantable and active implantable medical devices and their accessories covered by Regulation (EU) 2017/745; (b) fixed installed medical devices and their accessories covered by Regulation (EU) 2017/745; (c) medical devices and their accessories covered by Regulation (EU) 2017/745 and fitted with a built-in system visually displaying the instructions for use." Art. 3 (2) of the Commission implementing Regulation (EU) 2021/2226: "(2) Manufacturers may provide instructions for use in electronic form instead of in paper form for the devices listed in paragraph 1 under the following conditions: (a) the devices and accessories are intended for exclusive use by professional users; and

		~~(a) the devices and accessories are intended for exclusive use by professional users; and~~ ~~(b) the use by other persons is not reasonably foreseeable.~~”			(b) the use by other persons is not reasonably foreseeable.”