

MEMORANDUM – 2 JULY 2021

EU/EEA MARKET ACCESS FOR “SWISS LEGACY DEVICES”
POST ABANDONMENT OF SWISS-EU MRAI. EXECUTIVE SUMMARY**Question submitted**

On 26 May 2021, the Medical Devices Regulation¹ (“**MDR**”) entered into force, repealing and replacing the Medical Devices Directives² (“**MDD**”). Article 120 MDR permits continued EU sales of certain MDD-compliant devices (“**Legacy Devices**”) after 26 May 2021 under certain conditions, in particular (i) a valid certificate demonstrating MDD compliance and (ii) compliance with obligations set out in the MDR on post-marketing surveillance, market surveillance, vigilance, registration of economic operators and of devices.

MedTech Europe asked us to assess how the abandonment of EU-Swiss negotiations on updating the chapter on medical devices in the EU/Swiss Mutual Recognition Agreement³ (“**MRA**”) and the “**Notice to Stakeholders**” published by the European Commission (“**Commission**”) on 26 May 2021⁴ impact manufacturers that are based in Switzerland, or have an Authorized Representative registered in Switzerland (“**CH AR**”), and that wish to continue EU sales of MDD-compliant medical devices that have a valid certificate granted prior to 26 May 2021, either by a Notified Body established in the EU, or by a recognised conformity assessment body established in Switzerland (“**Swiss Legacy Devices**”).

Assessment

As set out in Chapter II below, the Commission is obliged to use its voting powers in the Joint Committee established under the MRA to ensure the “smooth functioning” of the MRA. This includes good faith cooperation on updates to the MRA. By using that vote to block updates without a valid technical reason, it is misusing its powers.

The Commission’s unilateral decision to cease application of the MRA, and the Commission’s purported retrospective withdrawal of mutual recognition for Swiss Legacy Devices, as expressed in particular in the Notice to Stakeholders, are contrary to EU law, the MRA, and WTO law.

Instead of the position taken in the Notice to Stakeholders, Swiss Legacy Devices must be granted access to the EU/EEA market under the same conditions as all other Legacy Devices, and, with regard to reports, certificates, authorisations and conformity marks issued under the MRA, exactly as had been the case between 26 May 2017 and 26 May 2021. It follows directly from the MRA, which has remained in full force and effect after 26 May 2021, that Swiss Legacy Devices must be granted full “**Article 120 MDR rights**”:

¹ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

² Directive 93/42/EEC of 14 June 1993 concerning medical devices (“**MDD**”) and Directive 90/385/EEC of 20 June 1990 on active implantable medical devices (“**AIMDD**”) (collectively referred to as “**MDD**”).

³ Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment, OJ L 114, 30.4.2002, p. 369 (latest consolidated version available [here](#)).

⁴ Notice to Stakeholders: Status of the EU-Switzerland Mutual Recognition Agreement (MRA) for Medical Devices, https://ec.europa.eu/health/sites/default/files/md_dialogue/docs/mdcg_eu-switzerland_mra_en.pdf.

- The EU and its Member States must continue to permit EU sales of all MDD devices with a valid certificate issued by a Swiss conformity assessment body prior to 26 May 2021 and may not require an EU CE certificate as a condition for importation, as well as MDR-compliant devices put on the market in Switzerland;
- The EU and its Member States must recognise existing registrations of Swiss manufacturers and of Swiss authorised representatives in Switzerland, and may not require the appointment of an additional EU authorised representative (“EU AR”) nor may they require relabelling of products to reflect the addition of an EU AR;
- The EU and its Member State authorities must continue, for Legacy Devices including Swiss Legacy Devices, to cooperate with their Swiss counterparts, and must grant access to Eudamed.

Any decision or act by an EU institution or Member State authority to set aside these obligations infringes Article 120 MDR and the MRA. The (non-binding) Notice to Stakeholders, which has no legal basis, amounts to an attempt to improperly circumvent EU law in Article 120 MDR, and a ‘call to abandon an international treaty’ (i.e., MRA), which is surprising given the emphasis that the EU has placed on “*pacta sunt servanda*” vis-à-vis the United Kingdom.

Conclusion

It follows from the analysis that the Commission’s call for an abrupt cessation of compliance with the MRA, and the purported retroactive withdrawal of mutual recognition already granted prior to 26 May 2021 for assessments, certificates and authorisations of Swiss Legacy Devices, are contrary to a range of procedural and substantive provisions of EU and international law.

The Commission’s refusal to cooperate within the Joint Committee to ensure the smooth functioning of the MRA by duly updating the MRA Annexes – in particular by using its veto powers in the Joint Committee to refuse either to assess new Swiss legislation or to include it in Annex 1 to the MRA, which has apparently been ongoing for several years – also infringes EU and international law. Moreover, that refusal raises the broader risk that, if the EU has undermined the MRA for medical devices, abandoning it gradually, the EU might assume the same can be done for all other 19 MRA product chapters and, indeed, for additional bilateral treaties amongst the more than 120 such treaties concluded between the Parties.

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II. ASSESSMENT

2.1 Introduction

1. This chapter sets out why the EU and its Member States must continue to grant full market access rights and “Article 120 MDR rights” to Swiss Legacy Devices. It discusses, in turn, the scope of Article 120 MDR rights and the questions submitted to us (2.2); the purpose and legal effects of MRAs in general (2.3); the continued legal effect of the EU-Swiss MRA (2.4), which is not affected by the Commission’s unilateral press release and Notice to Stakeholders of 26 May 2021 (2.5); the specific obligations imposed on the EU and its Member States by the MRA and its Annex 1, Chapter 4 on medical devices in relation to devices assessed for conformity with the MDD (2.6); how the EU and its Member States have given effect to the MRA (2.7); and the various infringements of EU and international law that would occur if the EU and its Member States would follow the approach asserted by the Commission on 26 May 2021, i.e., the unilateral withdrawal of mutual recognition for Swiss Legacy Devices for which the certificates and authorisations had already been recognised prior to 26 May 2021 (2.8).

2.2 Article 120 MDR rights and questions submitted

2. The MDR became fully applicable on 26 May 2021. The MDR has repealed and replaced the MDD as of 26 May 2021.
3. Article 120 MDR sets out transitional provisions, permitting a temporary continuation of EU/EEA market access for medical devices that were regulated under the MDD prior to 26 May 2021, and can demonstrate continued MDD compliance (hereinafter: “**Legacy Devices**”).
4. Article 120(2) MDR provides that certificates issued by a notified body in accordance with the MDD before 25 May 2017 remain valid until they expire or, for certain certificates, at the latest on 27 May 2022. It also provides that certificates issued from 25 May 2017 remain valid until they expire or at the latest on 27 May 2024.
5. Article 120(3) MDR provides that manufacturers of devices with valid MDD CE certificates or Class I device with a Declaration of Conformity drawn up under the MDD before 26 May 2021 and which will be ‘up-classified’ under the MDR may continue to place their devices on the EU/EEA market or to put them into service until 26 May 2024 provided they meet certain conditions, i.e.:
 - a. the medical devices continue to comply with the MDD;
 - b. there is no significant change in the design and intended purpose of the medical device;
 - c. the manufacturer complies with the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices.

6. Article 120(4) of the MDR provides that devices placed lawfully on the EU/EEA market under the MDD, or by virtue of Article 120(3) of the MDR, may continue to be made available on the EU/EEA market until 27 May 2025 (so-called “sell-off” provision).
7. The EU/EEA market access rights granted under Article 120 MDR will hereinafter be referred to as “**Article 120 MDR rights**.”
8. The question submitted to us is, in essence, whether Article 120 MDR rights can be invoked for Swiss Legacy Devices following the Commission’s press release of 26 May 2021 and Notice to Stakeholders. In the press release, the Commission announced the MRA had “*ceased to apply*”:

“Today, the Commission has published a notice to stakeholders informing them that the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland ceased to apply on 26 May. This is linked to the new Medical Devices Regulation entering into force in the EU on the same date”⁵ [emphasis added].
9. In its (non-binding) Notice to Stakeholders of the same date, the Commission asserts that Swiss Legacy Devices cannot benefit from the Article 120 MDR rights because such devices are no longer covered by certificates that the EU must recognise:

“existing certificates issued under the MRA will no longer be recognised as valid in the EU.”
10. The Notice to Stakeholders also asserts that the EU will disregard registrations of Swiss manufacturers and CH AR appointed by manufactures outside Switzerland (it states that “*Swiss manufacturers and third country manufactures whose authorised representative was previously established in Switzerland, must appoint an EU authorised representative*” and “*comply with the requirements on registration and labelling of products*”).
11. Neither the press release nor the Notice to Stakeholders provides a substantiation or legal basis for the assertions included therein. The press release and the Notice to Stakeholders merely refer to the failure to reach an agreement on an overarching Institutional Framework Agreement (“**IFA**”), and a purported failure of the EU and Switzerland to agree on an update to the medical devices chapter of the MRA before 26 May 2021.
12. The position taken by the EU with regard to the cessation of cooperation on market surveillance activities is not clear. On the one hand, the EU website for recognised conformity assessment bodies still mentions the Schweizerische Vereinigung für Qualitäts- und Managementsysteme (“**SQS**”) and its recognition under the MDD (with a pop-up stating that SQS can still “*carry out market surveillance activities*”).⁶

⁵ Press release IP/21/2684 of 26 May 2021, “Commission publishes information notice on the status of the EU-Switzerland Mutual Recognition Agreement for Medical Devices”, accessible [here](#).

⁶ The pop-up on the Nando webpage states: “*Warning: As from 26 May 2021, the Notified Body [SQS] is no longer able to issue new certificates under Directive 93/42/EEC, but only allowed to carry out market surveillance activities validly issued under that Directive during the transitional period, as established in Article 120 of*

13. On the other hand, it appears that the Commission has, in the meantime, ended the Swiss authorities' access to the EU's safety database Eudamed, which had existed since 2002: in its Notice to Stakeholders, the Commission stated that "*the Swiss national competent authority is not registered in Eudamed as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices as of 26 May 2021.*"⁷
14. MedTech Europe seeks to understand the extent to which Article 120 MDR rights can be relied on, as a matter of EU and international law, by manufacturers of Swiss Legacy Devices, and in particular the following categories of manufacturers:
- (i) Swiss-based manufacturers which manufacture Class I devices and with Declarations of Conformity drawn up in compliance with the MDD before 26 May 2021 (who would be reliant on Article 120(3) MDR);
 - (ii) Swiss-based manufacturers with MDD CE certificates from EU/EEA notified bodies (who would be reliant on Article 120(2) MDR);
 - (iii) ex-Swiss/ex-EU/ex-EEA-based manufacturers with a CH AR (who would be reliant on Article 120(2) or (3) MDR, depending on the circumstances); and
 - (iv) manufacturers with MDD CE certificates issued by Swiss notified bodies (who would be reliant on Article 120(2) MDR).
15. All those manufacturers seek to ensure, in particular, that the certificates on which they rely for placing Swiss Legacy Devices on the EU/EEA market continue to be regarded as "*Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC,*" so that they "*shall remain valid*" as set out in Article 120(2) MDR, and, as a consequence, can also benefit from Article 120(3) MDR.⁸
16. As set out in the following paragraphs, the EU and its Member States must grant continued market access rights for Swiss Legacy Devices under Article 120 MDR, on the same basis as all other Legacy Devices.

2.3 Introduction to MRAs

17. In order to appreciate the purpose and legal effects of MRAs, it is useful to recall their origins, which can be traced back to the Council resolution of 7 May 1985 on a new approach to technical harmonization and standards (85/C 136/01)⁹ to be applied **within the Community**. In this resolution, the Council stated that "*the new approach should be accompanied by a policy on the assessment of conformity*" based on "*the*

Regulation (EU) 2017/745." See https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe_cd=EPOS_49878, last consulted on 27 June 2021.

⁷ See Commission, MDR/IVDR ACTOR MODULE FAQs (June 2021 v1.3), available [here](#), see section 1.3. The FAQ also notes: "*The national competent authorities from EU 27, Iceland, Liechtenstein and Norway are registered in EUDAMED as well as the UK competent authorities in respect of Northern Ireland. Concerning other third countries national competent authorities, the Commission may in principle be able to register them in the actor module from a later date under the condition that an international agreement including the MDR (and in due course the IVDR) has been concluded or fully updated.*" section 1.1 (emphasis added).

⁸ Article 120(3) MDR grants rights in relation to a "*device with a certificate which is valid by virtue of paragraph 2 of this Article.*"

⁹ Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:1985:136:FULL&from=EN>.

principle of mutual recognition of proofs of conformity” in order to ensure mutual recognition and free movement of those goods within the Community.

18. A “new approach” was also to be applied to the Community’s trading partners: *“in its relations with third countries the Community will endeavour to promote international trade in regulated products, in particular by concluding mutual recognition agreements.”*
19. In the Commission Communication of 15 June 1989 (89/C267/03), entitled “A global approach to certification and testing, Quality measures for industrial products,”¹⁰ the Commission emphasised that the new approach of harmonised technical standards and mutual recognition of proofs of conformity assessments within the Community would require a **common external approach**, because of the *“obligation for Member States under Community law to accept products, including third country products, lawfully marketed in another Member State.”*
20. This common external approach was to take the form of mutual recognition agreements to be negotiated by the Commission, taking *“as a starting point”* the Community’s obligations under the WTO’s Agreement on Technical Barriers to Trade (**“TBT Agreement”**), which encourage WTO Members to conclude mutual recognition agreements.
21. In January 1995, the Commission initialled its first MRA negotiations with Switzerland. By June 1997, negotiations had been initialled with Japan, Australia, New Zealand, the United States, and Canada.
22. Prior to concluding the first MRAs, the Commission issued two Notes regarding the “assessment and supervision of systems applying to Conformity Assessment Bodies” (**“CABs”**)¹¹ and “Implementation of Mutual Recognition Agreements on conformity assessment (MRA)”¹² (**“Implementation Note”**). The Implementation Note succinctly recalls what MRAs are, and what they are for:

“Mutual Recognition Agreements in relation to Conformity Assessment (MRA) (...) are government-to-government agreements according to which the importing country accepts certification of compliance to its legal/regulatory requirements performed in the exporting country. (...)

*Thus, the authorities of the importing country **will accept** a conformity certificate delivered by a Conformity Assessment Body located in the exporting country (i.e. a domestic certification body that is designated by the authorities of one Agreement Partner and recognised by the other), without*

¹⁰ Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_.1989.267.01.0003.01.ENG&toc=OJ%3AC%3A1989%3A267%3ATOC.

¹¹ Specifications concerning assessment and supervision of systems applying to Conformity Assessment Bodies (CABs) with a view to their designation under MRAs Document Certif. 96/1 of 26.06.1996. See https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en.

¹² Implementation of Mutual Recognition Agreements on conformity assessment (MRA) and Protocol on European Conformity Assessment (PECA) Document Certif. 98/7 of 24.07.1998. See https://ec.europa.eu/growth/single-market/goods/international-aspects/mutual-recognition-agreements_en; available at (<https://ec.europa.eu/docsroom/documents/6417?locale=nl>).

need for additional technical evaluation/administrative intervention” [emphasis added].

23. The Implementation Note also explains the main actors that need to play their role in implementing MRAs, in order to ensure that the MRAs work for manufacturers, who are ultimately the beneficiaries of the MRAs:

“The main actors in the context of MRA are (...) the Community and the third country; they are the legal contractors and must ensure the fulfilment of the obligations of the agreement via the Joint committee; the Designating Authorities of the Parties (...), the Designated Bodies, CABs (...), and “The Industry, particularly manufacturers exporting to the Parties. They are the clients of CABs and, ultimately, the beneficiaries of the Agreements.” (emphasis added).

24. The Implementation Note further lists “a number of activities” that “shall already be carried out ideally before the operational start/implementation of the Agreements.” These activities cover the exchange of information, the clarification of criteria, programmes for confidence building, and designation of CABs.
25. The first MRAs were concluded on 17 August 1998 with Australia and New Zealand. Following these MRAs, the Resolution of the Council of 24 June 1999 on the management of Agreements on mutual recognition (1999/C190/02) reiterated the objective of the MRAs that were concluded and those still under negotiation: “*the objective of these Agreements is to provide effective market access throughout the territories of the Parties for all products covered by the Agreements.*”¹³
26. The Community proceeded to conclude MRAs with Israel (1999), the United States (1999), Japan (2001), Switzerland (2002) and Canada (2017).

2.4 The MRA continues to have full force and effect

27. The MRA is one of 120 bilateral treaties concluded between Switzerland, on the one hand, and the European Community (now the EU) on the other hand. The MRA forms part of a series of seven agreements in the sectors free movement of persons, air and land transport, public procurement, scientific and technological cooperation, and trade in agricultural products. All these agreements entered into force, simultaneously, on 1 June 2002.
28. Article 21(3) MRA provides: “*This Agreement shall be concluded for an initial period of seven years. It shall be tacitly extended, unless the Community or Switzerland notifies the other Party to the contrary before the expiry of that period.*” Since no such notice was provided by the Community or by Switzerland before 1 June 2009, the MRA was prolonged for an indefinite duration on that day.
29. Article 10(4) MRA establishes a Committee on mutual recognition in relation to conformity assessment, which decides by “*mutual agreement*” (hereinafter “**Joint Committee**”). The Joint Committee is empowered to establish sector-specific rules for the mutual recognition of twenty product sectors, which are included in Annex 1

¹³ See [https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX:31999Y0707\(01\)](https://eur-lex.europa.eu/legal-content/CS/TXT/?uri=CELEX:31999Y0707(01)).

(entitled “Product Sectors”). The chapter relevant to our analysis is Chapter 4 – Medical Devices, which was updated most recently on 2 December 2017 by Decision 2/2017 of the Joint Committee).¹⁴

30. The MRA contains procedures for revising, suspending and terminating the MRA and its Annexes (which, pursuant to Article 16 MRA “*shall form an integral part thereof.*”
- Article 18(1) (entitled: “Revision”) provides that “*[i]f a Party wishes to have this Agreement revised, it shall inform the Committee. Modifications to this Agreement shall enter into force after the respective internal procedure have been completed.*”
 - Article 19 (entitled “Suspension”) provides that “*[w]here a Party establishes that the other Party is failing to comply with the conditions of this Agreement, it may, after consulting the Committee, suspend application of Annex 1 in full or in part.*” Article 21(3) provides that “*[t]he Community or Switzerland may denounce this Agreement by notifying the other Party. Where such notification is given, the provisions of paragraph 4 shall apply.*”
 - Article 21(4) provides that “*[t]he seven agreements referred to in paragraph 1 shall cease to apply six months after receipt of the non-renewal notice described in paragraph 2 or the denunciation notice described in paragraph 3.*”
 - Article 20 MRA (entitled: “Acquired Rights”) provides that “*[t]he Parties shall continue to recognise reports, certificates, authorisations and conformity marks and manufacturers’ declarations of conformity issued in accordance with, and prior to the expiry of, this Agreement, provided that the request for conformity evaluation to be started was made before the notice of non-renewal or denunciation was given.*”

NB: The wording of Article 20 MRA would certainly cover the recognition of “*Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC,*” as provided for in Article 120(2) and (3) MDR, on which manufacturers of Swiss Legacy Devices seek to rely (see point 15 above).

31. We understand that the Commission has not informed the Joint Committee of a wish to have the MRA revised. The Commission has not consulted the Joint Committee with a view to suspending application of any part of Annex 1. The Commission has not submitted a notice of denunciation to the Switzerland. Therefore the MRA and its entire Annex 1 apply in full unless and until the procedures for revision, suspension or denunciation have been completed, with due observe of acquired rights.

¹⁴ Decision No 2/2017 of the Committee established under the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment of 22 December 2017 on the amendment of Chapter 2 on Personal protective equipment, Chapter 4 on medical devices, Chapter 5 on gas appliances and boilers and Chapter 19 on Cableway installations [2018/403] (available [here](#)).

2.5 MRA obligations are unaffected by the Commission's unilateral decision to cease applying the MRA; a withdrawal would infringe EU and international law

32. As set out in para. 2.2 above, the Commission has taken no steps to revise, suspend or denounce the MRA in accordance with the procedures set out in the MRA. In a press release of 26 May 2021, the Commission, as noted, nonetheless asserts that the MRA "ceased to apply on 26 May. This is linked to the new Medical Devices Regulation entering into force in the EU on the same date."¹⁵ [emphasis added].
33. However, in the absence of any step foreseen in the MRA, the Commission's press release (like the Notice to Stakeholders discussed below) has no legal basis or legal effect on the validity of the MRA or the rights and obligations that follow from the MRA – the Commission's decision can only be characterised as a unilateral decision to cease applying, and to cease complying with, the MRA.
34. It is surprising that an institution representing the EU, which is founded on the rule of law,¹⁶ and expounds that fundamental value with some regularity, would take the position that the EU can unilaterally decide to cease applying a valid international treaty by issuing a press release with a notice to stakeholders that has no formal legal basis or status.
35. The Commission's unilateral decision to cease applying the MRA infringes EU and international law in different ways. In particular, that decision infringes the MRA itself; Article 218(9) Treaty on the Functioning of the European Union ("TFEU") (which requires Council approval for any "*decision suspending application of an [international] agreement*"), and, potentially, certain procedural provisions of the Vienna Convention on the Law of Treaties of 23 May 1969¹⁷ ("**Vienna Convention**"), as set out in more detail at para. 2.8 below.
36. We note already at this point that any unilateral decision to cease applying the MRA (and without observing acquired rights) would likely be vulnerable under at least the first three of the four grounds for annulment of decisions of EU institutions, as set out in Article 263 TFEU, i.e., "*on [1] lack of competence, [2] infringement of an essential procedural requirement, [3] infringement of the Treaties or of any rule of law relating to their application, or [4] misuse of powers*" [numbers added].
37. Furthermore, any other act based on the Commission's unilateral decision would lack a legal basis, and would be vitiated by the same errors and vulnerable under the same grounds for annulment. For example, the same legal errors taint the Commission's decision to block access of Swiss authorities or Swiss manufacturers to the safety database on the false premise that the MRA has ceased to apply – whereas it has continued to apply in full force.

¹⁵ Press release IP/21/2684 of 26 May 2021, "Commission publishes information notice on the status of the EU-Switzerland Mutual Recognition Agreement for Medical Devices," accessible [here](#).

¹⁶ Article 2 TEU provides: "*The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights [...].*"

38. We also note a broader point, going beyond the specific questions submitted: the Parties are obliged to cooperate in good faith on *updates* to the MRA, as explained below.

2.6 International obligations imposed on the EU by the MRA

39. The MRA imposes a series of specific mutual recognition obligations on the EU. Mutual recognition is provided through different mechanisms, depending on whether the acts to be recognised are at **product** level (e.g., assessments and certificates, which are recognised from the moment they are validly issued), at **institutional** level (designating authorities and conformity assessment bodies) or **legislative** level (which require an assessment by the Committee on mutual recognition (“**Joint Committee**” established under Article 10 MRA to ensure the “smooth functioning” of the MRA)).

Product level (e.g. certificates): immediate recognition

40. Article 1 MRA obliges the EU and Switzerland to mutually recognise all “reports, certificates, authorisations and conformity marks”, i.e. including certificates issued by EU and Swiss conformity assessment bodies recognised in accordance with the procedures of the MRA and of the manufacturer’s declarations of conformity certifying conformity to the requirements of the other Party.
41. Such product-level acts are to be mutually recognised automatically as of the moment they are validly completed according to the applicable national regulations of the Parties. As soon as a Notified Body issues a new certificate, for example, that certificate is mutually recognised.
42. This obligation has applied unchanged to medical devices since 2002, and it applies irrespective of the origin of the devices (Article 4 MRA).

Updating institutional and legislative developments: Joint Committee procedure

43. Articles 10 and 11 MRA are key to the way that the recognition process operates, and they demonstrate that the MRA is not a one-off treaty. It is a ‘**living document**’, and its Annexes (which form an integral part of the MRA¹⁸) are meant to be continuously updated in order to maintain mutual recognition and the smooth functioning of trade, whilst accommodating updates to legislation made by one of the Parties.
44. Under Article 10, the Joint Committee is tasked with “*the management and monitoring of the smooth functioning of this Agreement*”. That task includes “*examining any legislative, regulatory and administrative provisions notified by one Party to another pursuant to Article 12 [entitled: “Information Exchange”], in order to assess their repercussions on the Agreement and to amend the appropriate sections in Annex 1*”.

¹⁸ See Article 16 MRA: “*The Annexes to this Agreement shall form an integral part thereof.*”

Institutional updates

45. Article 10 MRA, read together with Annex 1, Chapter 4 of the MRA (the product chapter for medical devices), shows how the MRA intends the Joint Committee process to work for designated authorities and notified bodies.
- When one of the Parties establishes a designated authority, it notifies that authority to the Joint Committee, which updates the “*list of conformity assessment bodies*” (see Annex 1, Chapter 4, Section II).
 - When one of the Parties designates a conformity assessment body, it notifies that body to the Joint Committee, which updates the “*list of conformity assessment bodies*” (Article 11(1)(b)).
 - When one of the Parties contests the technical competence of a conformity assessment body, the Committee decides on the potential withdrawal of that body (Article 10(4)(e)).

Legislative updates

46. The MRA functions in a similar fashion for new legislation. When one of the Parties adopts new legislation, it notifies the other Party under Article 12. Under Article 10(4)(e), the Committee will then “*examin[e] ... repercussions*” of that new legislation on the Agreement and amend the appropriate sections in Annex 1.
47. Read together with the obligation of the Committee to ensure a “*smooth functioning*” of the Agreement, and Article 26 of the Vienna Convention (treaties must be performed “*in good faith*”), it follows that, if the EU adopts new legislation, and Switzerland adapts its own legislation accordingly, the Committee will “*assess*” the relevant legislation and, if the respective legislation ‘matches’, i.e., is equivalent in terms of fulfilling the public health objectives, the Committee adds that legislation to Annex 1.
48. Any objections to updates should be of a technical nature related to the fulfilment of the public health objectives of conformity assessment.
49. It is inconsistent with the MRA for a Party to block a decision in the Joint Committee on the basis of extraneous political considerations, such as those that explicitly motivate the Notice to Stakeholders. In effect, the Commission is misusing its position in the Joint Committee to penalize Switzerland for the position that it has taken in bilateral negotiations that have nothing to do with the MRA. This is inconsistent with the EU’s duty to implement the MRA in good faith, to ensure the “smooth functioning” of the MRA. The application of the MRA, which was agreed in 2002, is not conditioned on the conclusion of an institutional framework agreement between the two Parties. Thus, the Commission’s position deliberately undermines and obstructs the MRA by misuse of powers (“*detournement de pouvoir*”).

Updating mechanisms duly followed until recently

50. The “smooth functioning” of the MRA has operated from 2002 until very recently, for all institutional and legislative updates to the MRA.

51. For updates regarding conformity assessment bodies and designated authorities, the Joint Committee has duly kept a list, amending it following notifications received.^{19 20}
52. For updates regarding legislation, smooth functioning has been achieved until recently. For example, Chapter 4 of Annex 1 was entirely replaced by **Decision 2/2017**, because the Committee had been notified about new legislation of the EU (the MDR, and in particular Chapter 4 on Notified Bodies, which was to enter into effect immediately in order to enable voluntary MDR assessments), and respective changes to the Swiss legislation (discussed below in more detail). The Committee took note of these pieces of legislation, considered they were equivalent, and added them to Annex 1.
53. The ‘mutual recognition update’ brought about by Decision 2/2017 is explained in recital 3:

*“The European Union has adopted a new Regulation on medical devices whose Chapter IV applies mandatorily from 26 November 2017 and a new Regulation on in vitro diagnostic medical devices whose Chapter IV applies mandatorily from 26 November 2017. Furthermore, manufacturers have the possibility to apply these Regulations on a voluntary basis as from this date. **Switzerland has amended its regulatory provisions deemed equivalent under Article 1(2) of the Agreement to the abovementioned provisions of European Union legislation mandatorily applicable from 26 November 2017”** (Decision 2/2017, Preamble, Section 3) [emphasis added].*

“Chapter 4, Medical devices, of Annex 1 should be amended to reflect these developments” (Decision 2/2017, Preamble, Section 3).

54. The reference, in recital 3, to Swiss “*regulatory provisions deemed equivalent*” to the MDR by Decision 2/2017 refers to the *Medizinprodukteverordnung (MepV) AS 2017-5935* of 25 October 2017,²¹ which updated the general *Medizinprodukteverordnung (MepV) SR 812.213* (Federal Ordinance on Medical Devices, hereinafter: “**MedDO**” by including a new chapter on conformity assessment bodies corresponding to Chapter IV MDR (entitled: “Notified bodies”).

Specific obligations under Decision 2/2017

55. Consequently, the MedDO, as updated by MepV AS 2017-5935, was added to Section 1 of Chapter 4, which lists the “provisions covered by Article 1(2)” of the MRA, which provides, as noted, that “*the Community and Switzerland (...) shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies.*”

¹⁹ Nando (New Approach Notified and Designated Organisations) Information System (<https://ec.europa.eu/growth/tools-databases/nando/>).

²⁰ See <https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ab.main>.

²¹ Published at <https://www.fedlex.admin.ch/eli/oc/2017/650/de>. Consolidated version of the current MepV is published at <https://www.fedlex.admin.ch/eli/cc/2020/552/de>.

56. Sections II *et seq.* of the new Chapter 4 (as introduced by Decision 2/2017) confirm that the mutual recognition obligations cover both MDD devices and voluntary MDR devices.
57. Section V(1), entitled “*Registration of the person responsible for placing devices on the market,*” provides that a manufacturer who places a MDD-compliant device on the market shall “*inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to*” in Article 14 MDD. This means that the manufacturer must register the address of their registered place of business and the description of the devices concerned. Where a manufacturer who places a devices on the market under their own name does not have a registered place of business, that manufacturer must designate an authorised representative.
58. Section V(1) further provides that “*the Parties shall reciprocally recognise that registration,*” and that “*the manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.*”
59. In other words, the EU must recognise Swiss registrations and CH ARs, and cannot require the appointment of an additional EU AR.
60. Section V(2), entitled “*Labelling of medical devices,*” provides that manufacturers of both Parties “*shall indicate their name or trade name and address on the label of medical devices*” and that “[t]hey shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.”
61. In other words, since 22 December 2017, the EU cannot require the appointment of an EU AR by manufacturers registered in Switzerland or by foreign (i.e., ex-Swiss/ex-EU/ex-EEA) manufacturers having a CH AR, and the EU cannot require relabelling of devices that comply with Section V(2).²² There is no carve-out or exception for any device that was lawfully placed on the market prior to 26 May 2021.
62. Section V(3) provides for information exchange and cooperation between the EU and Switzerland for all MDD devices and voluntary MDR devices. This includes the following:
- Exchange of information on incidents occurring following placing devices on the market, as referred to in Article 10 MDD, according to Article 102 MDR (which provides for the uniform application of the MDR), and according to Article 103 MDR (which establishes the MDCG)
 - The right of Switzerland to submit applications of expert laboratories for designation by the Commission in accordance with Article 106 of the MDR and 100 of the IVDR.

²² At the same time, Article 51 of the MedDO which obligates all manufactures from outside of Switzerland to appoint a CH AR is contrary to Annex 1, Chapter 4, Section V of the MRA. The appointment of a CH AR may only be requested from manufacturers from outside of the Swiss and the EU/EEA territory which have no EU AR.

63. Section V(4) provides that Swiss authorities shall have access to the European database, Eudamed, under the MDD and IVDD, but notably also according to Article 32 of the MDR and Article 30 of the IVDR. In return, the Swiss authorities are obliged to transmit to the Commission and/or body responsible for managing Eudamed the data provided for, *inter alia*, in Article 32 MDR and Article 30 IVDR collected in Switzerland for entry into Eudamed.

64. Section V(5) of Attachment B, entitled “Transitional provisions” provides for full mutual recognition and market access of all devices that comply with the MDR (including those for which the MDR has been applied voluntarily):

“By way of derogation to the legislation in Section I, devices which comply with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may be placed on the market of both Parties respectively.

By way of derogation to the legislation in Section I, notified bodies which are designated and notified in accordance with Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may carry out assessment procedures laid down in these regulations and issue certificates in accordance with these Regulations. Such certificates shall be recognized by the Parties.”

65. In conclusion, Decision 2/2017 updated the MRA to “MDR-readiness,” permitting continued mutual recognition of all certificates and authorisations for MDD devices, as well as all devices proven to be MDR compliant based on voluntary application of the MDR.

2.7 Implementation of the MRA in the EU legal order

66. The EU did not need to adopt any EU Regulation, Directive, or Decision within the meaning of Article 288 TFEU to give legal effect to the MRA. If the EU concludes international agreements such as MRAs, such agreements, under established case law, become “an integral part” of the European legal order and obtain, in Member States, the same rank as EU law, from their date of entry into force.²³

67. In addition, the abovementioned provisions of the MRA are textbook examples of provisions having “direct effect” and creating enforceable rights for individual companies. These provisions meet the “double test” set out in the CJEU case law for determining direct effect.²⁴ First, the purpose, spirit and general scheme of the international agreement must show that the agreement was *intended* to create such rights.²⁵ That first test is undoubtedly met in case of the MRA, as explained in para. 2.2. above. Second, the wording of the provisions invoked must be clear, precise and unconditional (‘self-executing’).²⁶ That second test is undoubtedly met for the MRA provisions, as well. Each of the provisions invoked is extremely precise, clear, and unconditional – at least ‘on par’, from the perspective of precision, clarity and

²³ See, for example, Case 181/73, Haegeman, EU:C:1974:41, Cases 21-24/72, International Fruit Company, EU:C:1972:115, and Case C-386/08, Brita, EU:C:2010:91.

²⁴ See, for an overview, F. Martines, Direct Effect of International Agreements of the European Union, European Journal of International Law, Vo. 25, Issue 1, February 2014, pp. 129-147 <https://academic.oup.com/ejil/article/25/1/129/497390>.

²⁵ See cases quoted at footnote 27.

²⁶ See, for example, Case C-240/09, Brown Bear, EU:C:2011:125.

unconditionality, with the fiscal provisions of the EEA Agreement that were found by the Court to have direct effect, creating rights for individuals.²⁷

68. In practice, the MRA has been given legal and practical effect in the EU legal order by the EU and its Member States as follows.

MRA-conform interpretation and application of EU law

69. From a legal perspective – absent any EU implementing acts - all EU institutions and Member States authorities have given full effect to the MRA since 2002, by interpreting and applying the MDD and MDR such that all MRA-related terms, such as “conformity assessment”, “notified bodies”, “certificates”, “authorisations” and “registration” of manufacturers, have been read as including the corresponding Swiss assessments, bodies, certificates, authorisations and registrations granted pursuant to the MRA. We will refer to this method as “**MRA-conform interpretation**”.
70. Paragraph 20 of the preamble to the MDR supports the view that an MRA-conform interpretation should be given to the MDR, wherever relevant. This paragraph states that the key terms used in the MDR are to be interpreted, in the interests of “legal certainty”, in line with well-established practice at EU and international levels. This paragraph, therefore, calls explicitly for a harmonious interpretation of key terms used in both the MRD and international instruments, such as the MRA.
71. To our knowledge at least 50 manufacturers that have a CH AR registered with Swissmedic, the Swiss National Competent Agency for Therapeutic Products. All such manufacturers have been treated, under the MRA-conform interpretation, as meeting EU law requirements relating to the presence of a manufacturer or an authorized representative.
72. Similarly, the Swiss conformity assessment body SQS, which has been included on the list of recognised conformity assessment bodies under Chapter 4 of Annex 1 of the MRA²⁸, has issued at least 85 product certificates under the MDD, for types of medical devices manufactured by 8 EU-based and 54 Swiss-based manufacturers, and covering at least 10 types of products put on the market by EU manufacturers, and 75 products of Swiss manufacturers. We understand that SQS achieved its national accreditation under the MDR on 28 January 2021,²⁹ but that SQS has not yet been added to the MRA list of recognised conformity assessment bodies that can carry out MDR assessments. Under the MRA-conform interpretation, all of the devices put on the market in the EU under these registrations and certificates have been treated as devices properly bearing a CE mark issued by a properly-accredited notified body meeting the requirements of EU law.
73. From this perspective, the Commission’s press release of 26 May 2021 and its Notice to Stakeholders can be seen as an announcement of ‘turning the clock back 19 years’ by abandoning MRA-conform interpretation. However, there is no legal basis for the Commission to cease applying the MRA or to abandon the MRA-conform

²⁷ See Case T-115/94, Opel Austria v. Council, EU:T:1997:3, para. 102.

²⁸ See <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/regulation-of-medical-devices/conformity-assessment-bodies.html>.

²⁹ See <https://www.sqs.ch/en/branches/medical/national-designation-mdr>

interpretation under EU law, least of all in a manner that fails to respect legal certainty.

74. The Commission's duty to continue the MRA-conform interpretation covers, in particular, the concept of "*certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC*" (the AIMDD and MDD) that is set forth in Article 120(2) MDR.
75. As the title to Article 120 MDR makes clear, this provision is intended to serve as a transitional measure to preserve the right to market devices that benefit from the relevant "*certificates*" issued under the AIMDD and MDD ("**two Directives**"). Paragraph 99 of the preamble underscores that the purpose of the provision is, by way of derogation from the new MDR requirements, to permit the continued marketing in the EU, for a limited period, of legacy devices that already benefit from "*certificates*" issued under the two Directives ("**beneficiary legacy devices**"). In respect of these devices, the provision, therefore, seeks to preserve legal certainty and acquired rights during a defined transitional phase.
76. Under an MRA-conform interpretation, the language cited above in Article 120(2) MDR must be understood to include "*certificates*" issued by (Swiss) notified bodies that, at the time the certificates were issued, were recognized by the EU, under Articles 1 and 5 of the MRA, as having the authority to issue such "*certificates*" for purposes of marketing devices in the EU under the two Directives. Under the terms of the MRA, these beneficiary legacy devices were marketed in the EU, because they were found by the EU to meet the requirements of the two Directives, and they may continue to be so marketed.
77. This MRA-conform interpretation of Article 120(2) MDR is also supported by Article 20 of the MRA, which requires the EU, in the event that the MRA is terminated (which it has not been), to "*continue to recognise reports, certificates, authorisations and conformity marks ... issued in accordance with*" the MRA. In the MRA, the EU has, therefore, committed to preserving legal certainty and acquired rights in respect of Swiss-issued "*certificates*" (and other instruments) that are recognized pursuant to the two Directives, even in the case of the termination of the MRA.
- NB: A good illustration on how acquired rights can be protected is the "pop-up" published on the Nando website for the Swiss conformity assessment body SQS, which can still "*carry out market surveillance activities*" (which are needed *inter alia* to monitor the safety of Legacy Devices).³⁰
78. Although Article 120(2) MDR permits the continued marketing of beneficiary legacy devices, the third sentence of Article 120(3) MDR qualifies that transitional marketing right. Specifically, the requirements of the MDR "*relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices*" apply in place of the corresponding requirements in the two Directives.

³⁰ The pop-up on the Nando webpage states: "Warning: As from 26 May 2021, the Notified Body [SQS] is no longer able to issue new certificates under Directive 93/42/EEC, but only allowed to carry out market surveillance activities validly issued under that Directive during the transitional period, as established in Article 120 of Regulation (EU) 2017/745." See https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.nb&refe_cd=EPOS_49878, last consulted on 27 June 2021.

79. As set out below, each of the four sets of MDR requirements mentioned in Article 120(3) involves administrative formalities relating, generally, to the gathering and provision of information in relation to devices and their associated economic operators. Each of the four MDR requirements is perfectly capable of being met in respect of beneficiary legacy devices. Indeed, beneficiary legacy devices **must**, in principle, be capable of complying with the four sets of MDR requirements. Otherwise, there would be an irreconcilable contradiction between two paragraphs of Article 120 MDR: the transitional marketing rights granted in paragraph (2) would be irrevocably denied because of the impossibility of meeting the requirements in paragraph (3). An interpretation that gives rise to such an inherent contradiction in adjacent paragraphs of a single provision is untenable.
80. Instead, to prevent the irrevocable denial of the transitional marketing rights in Article 120(2) MDR, the adjacent provisions of Article 120(3) MDR must be interpreted – and can be without difficulty – in a manner that enables the four MDR requirements to be met in respect of any beneficiary legacy devices.
81. The MDR requirements relating to “*post-market surveillance*” require manufacturers to maintain systems to gather, analyse and report data on product performance. Similarly, the requirements relating to “*vigilance*” call for manufacturers to gather and report information on the defective performance of devices. Under the relevant MDR definition, a “*manufacturer*” may be located in a third country. Thus, a Swiss-based manufacturer can perfectly well comply with these two requirements in relation to Swiss Legacy Devices that benefit from the transitional marketing rights in Article 120(2) MDR.
82. The MDR requirement relating to “*market surveillance*” requires the competent authorities to perform checks on the conformity characteristics and performance of devices, including on the basis of information secured from economic operators. The relevant competent authorities can readily meet these requirements in relation to Swiss Legacy Devices, including by requesting relevant information from a Swiss-based manufacturer.
83. Finally, the MDR requirements relating to the “*registration*” of devices and economic operators can also be met in relation to beneficiary legacy devices. The implementation of the MDR registration requirements depends, in the first instance, on the Commission itself. The Commission is obliged to create and maintain electronic systems for the registration of devices and economic operators. Evidently, the Commission is required, under EU law, to create systems that make the required registration of beneficiary legacy devices and their associated economic operators possible. Put differently, the Commission cannot create a system that makes it impossible for economic operators to fulfil the registration requirement in Article 120(3) in respect of beneficiary legacy devices that enjoy transitional marketing rights under Article 120(2). Under such an approach, the Commission’s conduct, in implementing the administrative requirements under Article 120(3), would improperly frustrate and circumvent the transitional marketing rights that the Union legislator has conferred in respect of beneficiary legacy devices. Again, such an interpretation is untenable.
84. Assuming that the Commission fulfils its EU law obligation to create a registration system that enables the registration of beneficiary legacy devices and their associated economic operators, Swiss-based economic operators will readily be able

to provide the information, and undertake the administrative tasks, needed to complete the registration process. In that respect, we understand that economic operators located outside the EU and Switzerland have been able to register. The same should apply to Swiss-based operators.

Other implementation measures

85. In addition to the MRA-conform interpretation of EU law, the proper implementation of the MRA has entailed, since 2002, a series of practical actions by the EU and its Member States and by Switzerland, as noted in the Implementation Notice quoted above.
86. First, the EU has cooperated, until recently, in good faith in the Joint Committee to ensure the “smooth functioning” of the MRA, and has contributed, for different Product Chapters, to the updates necessary to keep the MRA functioning smoothly.³¹
87. Second, since 2002, Swiss authorities have participated in the EU’s market surveillance activities, and they have been provided with access to Eudamed, the European database accessible to the Commission and Member State authorities. The database is an important tool for the market surveillance authorities and includes, *inter alia*, (i) data relating to registrations of manufacturers, authorised representatives and devices, (ii) data relating to certificates (issued, withdrawn, suspended, etc.) and (iii) vigilance data relating to reportable incidents.³²
88. Third, under the MDD, Swissmedic was involved in the drafting of MEDDEV guidelines. Switzerland was a “member” of the Medical Devices Experts Group (“MDEG”) together with Iceland, Norway and Liechtenstein as well as Turkey,³³ and the Agency participated in meetings and in the formulation of guidance documents. In particular, under the MDD, Swissmedic took part in the meetings of the EU Working Group Competent Authorities for Medical Devices (“CAMD”). Most notably, the Head of Swissmedic’s Medical Devices Division for several years chaired the CAMD Executive Group, the CAMD’s steering committee. Also with regard to CAMD there has been no official communication yet relating to Swissmedic’s future status..
89. Since the establishment of the MDCG and the drafting of guidance under the MDR and IVDR, Switzerland has had “observer” status together with Iceland, Norway, Liechtenstein and Turkey.³⁴
90. It appears that the Commission has ended Swissmedic’s access to Eudamed: in its Notice to Stakeholders, the Commission stated that “*the Swiss national competent authority is not registered in Eudamed as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices as of 26 May 2021.*”³⁵ The status of the other cooperation mechanisms is unclear. There has not

³¹ See chronological list of the 17 updates of the MRA published by the Swiss State Secretariat for Economic Affairs: <https://www.fedlex.admin.ch/eli/cc/2002/276/de/history>.

³² See Article 14a MDD.

³³ See overview of the MDEG’s members [here](#).

³⁴ See overview of the MDCG’s members [here](#).

³⁵ See Commission, MDR/IVDR ACTOR MODULE FAQs (June 2021 v1.3), available [here](#), see section 1.3. The FAQ also notes: “*The national competent authorities from EU 27, Iceland, Liechtenstein and Norway are registered in EUDAMED as well as the UK competent authorities in respect of Northern Ireland. Concerning other third countries national competent authorities, the Commission may in principle be able to register them in the*

been any official communication yet relating to Swissmedic's continuing status as "observer" under the MDCG, and the CAMD's website still lists Switzerland as a "member" in both CAMD's MDR/IVDR Implementation Taskforce³⁶ and the Transition Subgroup.³⁷

2.8 Infringements of EU and international law

91. As noted in para. 2.3 above, the Commission's decision to cease applying the MRA as of 26 May 2021 and its purported withdrawal of mutual recognition *already granted* prior to 26 May 2021 gives rise to multiple infringements of different procedural and substantive provisions of EU and international law.

Violation of Article 120 MDR

92. First, Article 120 MDR is violated by any EU institution or EU Member State authority or court that refuses to grant Article 120 MDR rights to Swiss Legacy Devices.

Infringements of the MRA

Failure to update

93. Second, by tying its approval of MRA updates to extraneous political considerations relating to a Joint Institutional Framework, the EU has infringed its obligations under Article 10 MRA to cooperate in good faith to achieve the updates necessary to keep the MRA functioning smoothly, and misused its voting powers on the Joint Committee ("détournement de pouvoir").

Procedural violations

94. Third, the unilateral refusal to apply the MRA directly infringes the MRA itself, because the MRA continues to apply as a matter of law, in full, unless and until one of the Parties follows the proper procedures set out in the MRA to revise, suspend or denounce the MRA; furthermore, in that case, the MRA preserves acquired rights, which the Commission's unilateral decision negates.

Violation of Article 1 MRA

95. Fourth, Article 1(1) MRA³⁸ and Article 1(2)-(3) MRA³⁹ are violated by any failure to afford mutual recognition to Swiss Legacy Devices.

actor module from a later date under the condition that an international agreement including the MDR (and in due course the IVDR) has been concluded or fully updated," section 1.1 (emphasis added).

³⁶ See <https://www.camd-europe.eu/mdr-ivdr-implementation/about-implementation-taskforce/>.

³⁷ See <https://www.camd-europe.eu/mdr-ivdr-implementation/about-transition-subgroup/>.

³⁸ Article 1(1) MRA provides: "The Community and Switzerland hereby grant mutual acceptance of reports, certificates, authorisations and conformity marks issued by the bodies recognised in accordance with the procedures of this Agreement (hereinafter recognised conformity assessment bodies) and of the manufacturer's declarations of conformity certifying conformity to the requirements of the other Party in the areas covered by Article 3."

³⁹ Articles 1(2) and 1(3) MRA provide as follows: "2. In order to avoid duplication of procedures when Swiss and Community requirements are deemed equivalent, the Community and Switzerland shall mutually accept reports, certificates and authorisations issued by recognised conformity assessment bodies and manufacturer's declarations of conformity certifying conformity to their respective requirements in the areas covered by Article 3.

Violation of MRA Annex, Chapter 4, Section V(1)

96. Fifth, the EU requirement to appoint an additional EU AR infringes Section V(1) of MRA, Chapter 4, which provides that the EU “*shall reciprocally recognise*” Swiss registrations of manufacturers and their CH AR.

Violation of MRA Annex, Chapter 4, Section V(2)

97. Sixth, the EU requirement to relabel Swiss Legacy Devices (e.g., by requiring an EU AR to be added to the label) infringes Section V(2) MRA, Chapter 4, which provides that Swiss manufacturers and CH ARs “*shall not be obliged*” to add an EU AR to the label.

NB: On this point, there does not appear to be a reciprocity issue: Article 25(4) MedDO still explicitly recognises CE Certificates issued by EU notified bodies.

Violation of MRA Annex, Chapter 4, Sections V(3) and (4)

98. Seventh, by ending cooperation and information exchange with Swiss authorities by excluding them access to Eudamed⁴⁰ (and possibly refusing MDEG, MDCG and CAMD cooperation as set out above()) the EU infringes the obligations of cooperation and information exchange set out in Sections V(3) and V(4) MRA, Chapter 4.

Violation of principle of legal certainty and legitimate expectations

99. Eighth, the retroactive withdrawal of mutual recognition already granted would also be contrary to the principle of legal certainty, which requires EU legislation to “*be certain and its application foreseeable by individuals and that every [EU] measure having legal effects must be clear and precise and must be brought to the notice of the person concerned in such a way that he can ascertain exactly the time at which the measure comes into being and starts to have legal effects. That requirement must be observed all the more strictly in the case of a measure liable to have financial consequences in order that those concerned may know precisely the extent of the obligations which it imposes on them.*”⁴¹
100. The same applies to the **principle of protection of legitimate expectations**, which is the corollary of the principle of legal certainty.⁴²

Reports, certificates, authorisations and manufacturer's declarations of conformity shall in particular indicate conformity with the Community legislation. Conformity marks required by the legislation of one of the Parties must be affixed to products placed on the market of that Party. 3. The Committee provided for in Article 10 shall specify the cases in which paragraph 2 shall apply.” NB: the Committee has specified these cases, most recently in Decisions 2/2017.

⁴⁰ See Commission Eudamed Actor Module FAQs (June 2021, v1.3) (available [here](#)), Question 1.3 which states that “*the Swiss national competent authority is not registered in EUDAMED as there is no longer a mutual recognition agreement between the EU and Switzerland for medical devices as of 26 May 2021. Switzerland is therefore considered as a nonEU country.*”

⁴¹ Case T-115/94, Opel Austria v Council, EU:T:1997:3, para. 6, and 74.

⁴² See Opinion of A-G Bot in Case C-519/07P, Commission v. Koninklijke Friesland Foods, EU:C:2009:256, para. 74-75: “74. The principle of the protection of legitimate expectations is a general principle of Community law which may be used to verify the legality of acts of the institutions. 75. As Advocate General Léger stated in his Opinion in Belgium and Forum 187 v Commission, (25) that principle can be seen as the corollary of the principle of legal certainty, which requires that Community legislation must be certain and its application foreseeable by

Infringement of Article 218(9) TFEU

101. Ninth, the Commission's unilateral decision to cease applying the MRA, without a prior decision by the Council, arguably infringes Article 218(9) of the TFEU, which provides that "[t]he Council, on a proposal from the Commission or the High Representative of the Union for Foreign Affairs and Security Policy, shall adopt a decision suspending application of an agreement and establishing the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement." It has been reported⁴³ that the Council's Legal Service insisted upon the proper application of Article 218(9) TFEU in the context of prolongation of 'grace periods' granted to the UK in the context of Brexit.

Violations of WTO law

102. Tenth, the EU's conduct offers a basis for several strong claims under the law of the World Trade Organization ("**WTO**").
103. The EU's measures amount to a "technical regulation" falling within the scope of the TBT Agreement. The EU appears to violate, at least, the following provisions of that Agreement:
- Article 2.1, setting out the non-discrimination obligation, because EU failed to rely exclusively on public health considerations while determining mutual recognition for Swiss goods, as it has done for third country goods such as those from Turkey;
 - Article 2.2, requiring that technical regulations should not be more trade restrictive than necessary to achieve a legitimate public objective, because the EU decision to withdraw mutual recognition is not based on public health considerations, as it should be, but on political considerations; and the withdrawal is effected on a retrospective basis;
 - Article 2.7, on the grant of equivalence, because EU's withdrawal of mutual recognition is not based on whether the goods fulfil the EU's public health objectives, but on political objectives;
 - Article 5.1 and its sub-paragraphs, on procedures for conformity assessment, for the same reasons mentioned in the context of Articles 2.2 and 2.7 above;
 - Article 6.1, on recognition of conformity assessments, because EU refuses to accept Switzerland's conformity assessments based on political considerations extraneous to public health.
104. In addition, the EU's measures also violate the following provisions of the General Agreement on Tariff and Trade 1994 ("**GATT 1994**"):

individuals, in the sense that it seeks, where a rule is altered, to ensure the protection of situations legitimately entered into by one or more natural or legal persons in particular."

⁴³ See <https://www.rte.ie/news/analysis-and-comment/2021/0626/1231417-brexite-analysis/>.

- Article I:1, because the EU discriminates against Swiss goods, by denying them mutual recognition based on the same factors applied to third country goods, i.e., public health considerations.
- Article X:3(a), which requires “uniform, impartial and reasonable” administration of laws and regulations affecting international trade, because (i) the Commission’s Notice to Stakeholders lacks any basis in EU law, and (ii) the EU measure is based on political considerations extraneous to public health.

Potential infringement of Article 42 of the Vienna Convention

105. Eleventh and last, even if the Commission’s decision were regarded as a “withdrawal” from, the MRA (a position we do not hold), that decision would infringe Article 42 of the Vienna Convention on the Law of Treaties of 23 May 1969 (“**Vienna Convention**”),⁴⁴ which provides the following: “*The termination of a treaty, its denunciation or the withdrawal of a party, may take place only as a result of the application of the provisions of the treaty or of the present Convention. The same rule applies to suspension of the operation of a treaty*”, and, if a termination, denunciation or withdrawal were to be done without respecting acquired rights, the EU would also infringe Article 70 of the Vienna Convention, which provides that “*Unless the treaty otherwise provides or the parties otherwise agree, the termination of a treaty under its provisions or in accordance with the present Convention (...) does not affect any right, obligation or legal situation of the parties created through the execution of the treaty prior to its termination.*”

III. CONCLUSIONS

106. It follows from the above that the Commission’s call for abrupt cessation of compliance with the MRA, and the purported retroactive withdrawal of mutual recognition already granted prior to 26 May 2021 for assessments, certificates and authorisations of Swiss Legacy Devices, are clearly contrary to a range of procedural and substantive provisions of EU and international law.
107. The Commission’s refusal to cooperate within the Joint Committee to ensure the smooth functioning of the MRA by duly updating the MRA Annexes – in particular by using its veto powers in the Joint Committee to refuse either to assess new Swiss legislation or to include it in Annex 1 to the MRA, which has apparently been ongoing for several years – is also incompatible with EU and international law. That refusal, moreover, raises the broader risk that, if the EU has undermined the MRA for medical devices, abandoning it gradually, the EU might assume the same can be done for all other 19 product chapters and, indeed, for other bilateral treaties concluded between the Parties. This could potentially undermine additional bilateral treaties amongst the 120 bilateral treaties the Swiss Federal Council wishes to preserve (and, if possible, even expand) according to its statement published on 26 May 2021.⁴⁵

⁴⁵ Press release by the Federal Council of 26 May 2021 (<https://www.admin.ch/gov/en/start/documentation/media-releases.msg-id-83705.html>): “At its meeting on 26 May, the Federal Council undertook an overall evaluation of the outcome of the negotiations on the institutional framework agreement (InstA). It concluded that there remain substantial differences between Switzerland and the EU on key aspects of the agreement. The conditions are thus not met for the signing of the agreement. The

* * *

Federal Council today took the decision not to sign the agreement, and communicated this decision to the EU. This brings the negotiations on the draft of the InstA to a close. The Federal Council nevertheless considers it to be in the shared interest of Switzerland and the EU to safeguard their well-established cooperation and to systematically maintain the agreements already in force. It therefore wishes to launch a political dialogue with the EU on continued cooperation. Meanwhile, it has tasked the Federal Department of Justice and Police (FDJP) to consider how autonomous amendments to Swiss legislation might contribute to the stabilisation of Swiss–EU relations.”