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Deadline extension for medical devices

Right objective, wrong approach

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The Medical Devices Regulation of 2017 establishes new rules for the authorisation of medical devices - from reading glasses to cardiac catheters. As of 26 May 2020, by contrast with the current situation, many low-risk class I devices, e.g. scalpels, will also have to be authorised by a "notified body". Instead of the 50 that currently exist, under the new law there are only eight "notified bodies" EU-wide to date .

- The new transitional provision relating to class I products, proposed by the Council on 25 November 2019, is necessary in order to avoid shortages of medical devices and thereby guarantee patient safety.
- The Council's planned approach for "corrigendum" of the Medical Devices Regulation is procedurally questionable because the meaning of the Regulation will be amended. A repeal by the European Court of Justice would have worse consequences. It is therefore necessary to amend the Regulation in accordance with the ordinary legislative procedure. This is easily possible within the time remaining.
- The EU Commission must submit the draft amending Regulation no later than January 2020. The European Parliament and the Council should then pass it by way of the urgency procedure.

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1 Introduction

The Medical Devices Regulation (MDR)[1] is to improve the safety and quality of medical devices, partly in reaction to scandals regarding breast implants, hip implants and mesh implants for women. It aims to ensure patient safety and at the same time promote innovation.[2] The Regulation came into force on 25 May 2017. It will apply as of 26 May 2020[3] and replaces inter alia the Directives on medical devices.[4] Transitional provisions are aimed at helping those affected to adapt to the new rules.

Medical devices are divided into four risk classes[5] and, until now, the vast majority of medical devices is classified as risk class I – the lowest risk class. Examples of class I devices are reading glasses and thermometers. Class III contains e.g. cardiac catheters and hip-joint implants.[6] Medical devices must be authorised for the EU internal market and undergo a comprehensive procedure according to their risk level. To ensure compliance with the statutory requirements, the involvement of a "notified body" may be required. As before, conformity assessment bodies - such as TÜV, DEKRA, BSI (Netherlands), IMQ (Italy) and others - may apply for notified-body status.

The new Medical Devices Regulation not only significantly tightens the rules applicable to the manufacturers of medical devices but also the requirements applicable to notified bodies.[7] As of 26 May 2020, all existing notified bodies that have not been re-designated and re-notified will lose their power to authorise medical devices. This creates problems: There are currently about 50 notified bodies EU-wide but only eight[8] have so far successfully completed the designation procedure under the new law. In view of the high number of medical devices,[9] it already looks certain that there will not be enough notified bodies to ensure prompt processing of authorisation applications. The supply of certain medical devices to the European market will therefore be at risk as of 26 May 2020. The situation is particularly difficult for class I products which, for the first time, under the new law, require the involvement of a notified body for their authorisation.

Those affected most on the demand-side are users of medical devices - hospitals, doctors - and in particular their patients; on the supply-side it is the manufacturers of medical devices who are affected. The Member

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1 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices as amended on 3 May 2019; available for download at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0745-20170505&from=EN> (last accessed: 17 December 2019).

2 See Recital 1 of the Medical Devices Regulation.

3 Art. 123 (2) Medical Devices Regulation.

4 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. For this see also Art. 122 Medical Devices Regulation.

5 Art. 51 (1) in conjunction with Annex VIII Medical Devices Regulation.

6 Research Service of the German Bundestag, "Marktzugangsvoraussetzungen für Medizinprodukte in der EU nach derzeitiger und künftiger Rechtslage", 2019, p. 6, footnote 14, <https://www.bundestag.de/resource/blob/651548/d854584693a9a0348fcdbaf9ee1351c5/WD-9-034-19-pdf-data.pdf> (last accessed: 17 December 2019).

7 See in general the Information from the Irish and German delegations, "Medical devices: Implementation of Regulation (EU) 2017/745 on medical devices (MDR)", June 2019, p. 4, <https://data.consilium.europa.eu/doc/document/ST-9774-2019-INIT/en/pdf> (last accessed: 17 December 2019).

8 One of which, however, is based in the United Kingdom.

9 Often put at 400,000 to 500,000 although the data does not allow for a conclusive figure. Regarding the number, see for example, German Council of Economic Experts (Sachverständigenrat) on the evaluation of developments in the health sector "Bedarfsgerechte Versorgung – Perspektiven für ländliche Regionen und ausgewählte Leistungsbereiche, Gutachten 2014", p. 142, para. 106, <https://www.svr-gesundheit.de/fileadmin/user_upload/Gutachten/2014/SVR-Gutachten_2014_Langfassung.pdf> (last accessed: 17 December 2019).

States with the largest medical technology sectors - based on industry turnover - are Germany, Ireland and France.[10]

The Council, in which the responsible ministries of the Member States are represented, wants to solve this problem with a correction - a "corrigendum" - of the Medical Devices Regulation. It is aimed at introducing an additional transitional provision for class I products.[11]

This cep**Adhoc** will first explain the new provisions on notified bodies (Section 2) and the transitional provisions (Section 3). The need to amend the transitional provisions will then be considered (Section 4), and the proposed approach involving a "corrigendum" of the Medical Devices Regulation will be assessed (Section 5).

2 The designation and notification of notified bodies

As of 26 May 2020, the existing notified bodies will lose their existing powers.[12] This means that the conformity assessment bodies will now have to be re-designated under the Medical Devices Regulation. The procedure is highly complex: Conformity assessment bodies must apply for their designation to the responsible authority in the Member State. This authority must assess the application, pass it on to the EU Commission and issue a preliminary assessment report. A joint assessment team, which includes external experts, is set up according to a fixed procedure. This team reviews the documentation and inter alia, together with the national responsible authority, carries out an on-site assessment of the applying conformity assessment body. The national responsible authority then submits a final assessment report and the draft designation. A final opinion on this and a recommendation with regard to the draft designation are issued at European level which the national responsible authority must duly take into consideration. Member States are only permitted to designate the conformity assessment body and notify the designation to the EU Commission when this procedure has been completed.[13] Based on initial experiences, the procedure is expected to take about 13 months, on average.[14]

[10] For this see the figures relating to "Medical Technology in Europe" in SPECTARIS German Industry Association for Optics, Photonics, Analytical and Medical Technology, "Die deutsche Medizintechnik-Industrie, SPECTARIS Jahrbuch 2018", 2018, p. 12, <https://www.spectaris.de/fileadmin/Infothek/Medizintechnik/Zahlen-Fakten-und-Publikationen/SPECTARIS_Jahrbuch_2018_Final.pdf> (last accessed: 17 December 2019).

[11] See Council of the European Union "Corrigendum", 25 November 2019, p. 44, <https://data.consilium.europa.eu/doc/document/ST-13081-2019-INIT/en/pdf> (last accessed: 17 December 2019).

[12] Art. 120 (1) Medical Devices Regulation.

[13] For details of the designation procedure see Art. 38-42 Medical Devices Regulation.

[14] See Federal Government "Antwort auf Kleine Anfrage 'Auswirkungen der neuen Medizinprodukteverordnung auf kleine und mittlere Unternehmen'", 12 July 2019, BT-Drs. 19/11541, p. 5, <http://dipbt.bundestag.de/dip21/btd/19/115/1911541.pdf> (last accessed: 17 December 2019).

3 Transitional provisions

3.1 Existing transitional provisions

In principle, the following transitional provisions apply:[15]

Date of authorisation certificate	Assessment carried out	by notified body	Validity of authorisation expires
Before 25 May 2017	under old law	under old law	Date indicated in the authorisation certificate.
25 May 2017 – 26 May 2020[16]	under old law	under old law	Date indicated in the authorisation certificate, with a maximum of five years from the issue date and no later than 27 May 2024.
As of 26 May 2020	under new law	under new law	Date indicated in the authorisation certificate, with a maximum of five years.

Thus, as of 26 May 2020, authorisation certificates can only be issued under new law and only by notified bodies that meet the requirements of the new law. Authorisation certificates issued between 25 May 2017 and 26 May 2020 cease to be valid no later than 27 May 2024.[17]

These transitional provisions do not, however, apply to medical devices for which no involvement of a notified body was envisaged under old law, as a result of which they did not receive an authorisation certificate from a notified body. In such cases, manufacturers could carry out conformity assessment procedures independently, attach the CE symbol to their devices and sell them on the market.

3.2 New transitional provision

The corrigendum proposed by the Council puts forward a new transitional provision for these class I devices that under old law[18] did not require a notified body for authorisation but do under the new law. Under the new transitional provision, such devices will basically be permitted to be brought onto the market and put into service up until 26 May 2024.[19]

4 Need for amendment of the transitional provisions

This document will not analyse whether the Medical Devices Regulation results in safer and better quality medical devices. If the social aim is to guarantee greater safety, then this cannot be put at risk during the period required for the process of adaptation that the industry needs to go through. The aforementioned transitional provisions, which provide legal protection ("grandfathering"), serve to support this process of change and are therefore essential.

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15 For full details see Art. 120 and Art. 56 (2) Medical Devices Regulation. See also EU Commission, "Transition Timelines from the Directives to the Regulations Medical Devices and in vitro Diagnostic Medical Devices", <https://ec.europa.eu/docsroom/documents/34907/attachments/1/translations/en/renditions/native> (last accessed: 17 December 2019).

16 Authorisation during this period is also possible under new law and by a notified body under new law in principle.

17 Art. 120 (2), sub-para. 2 Medical Devices Regulation.

18 It only refers, however, to Council Directive 93/42/EEC of 14 June 1993 relating to medical devices.

19 See Council of the European Union "Corrigendum", 25 November 2019, p. 44, <https://data.consilium.europa.eu/doc/document/ST-13081-2019-INIT/en/pdf> (last accessed: 17 December 2019).

The current transitional provisions in the Regulation are, however, inadequate: Under old law, there are currently still 50 notified bodies[20], under new law, on the other hand, only eight notified bodies have been notified[21] since the end of 2017[22]. The EU Commission identified this possible risk as early as 2012.[23] One reason for the decrease in numbers is that the conformity assessment bodies have to meet higher standards.[24] As a result, some notified bodies are no longer seeking designation under the new law.[25]

This will hinder manufacturers' access to the EU internal market, at least in the short term, both as regards certain existing devices and for new medical devices because the current sharp fall in the number of notified bodies will mean longer waiting times for the desired certificate of conformity. In addition, a notified body is only permitted to carry out the conformity assessment procedure for the types of medical device for which it has been designated.[26] Thus, it is difficult enough, particularly for manufacturers, to find a notified body to engage at all, which can carry out the relevant conformity assessment procedure within the remaining time period.[27]

An additional problem stems from the higher standards applicable to the clinical assessment of medical devices[28] which aims to ensure that only medical devices with a high level of safety can be offered on the EU internal market. This may hamper innovation because manufacturers first have to determine which standards they have to meet. This is currently also made more difficult by the fact that certain guidelines are still under development.[29]

As can be seen, a transition period ending in May 2020 was already too short because the EU Commission and Member States have not managed to create the necessary infrastructural foundations to enable inter

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20 See in this regard the relevant "Nando" database; EU Commission, "Notified bodies Nando", <https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13> (last accessed: 17 December 2019).

21 See in this regard the relevant "Nando" database; EU Commission, "Notified bodies Nando", <https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34> (last accessed: 17 December 2019). Of these, however, one notified body is based in the United Kingdom.

22 Art. 123 (3) (a) Medical Devices Regulation basically enables the designation and notification of conformity assessment bodies to be carried out from as early as 26 November 2017. This date also applied to the authorities which were to be designated by the Member States and responsible for the Medical Devices Regulation as well as for the deployment of the medical devices coordination group; see Art. 123 (3) (b) Medical Devices Regulation.

23 See EU Commission, "Proposal for a Regulation on medical devices", 26 September 2012, p. 182, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0542&from=EN> (last accessed: 17 December 2019).

24 See e.g. Research Service of the German Bundestag, "Marktzugangsvoraussetzungen für Medizinprodukte in der EU nach derzeitiger und künftiger Rechtslage", 2019, p. 12, <https://www.bundestag.de/resource/blob/651548/d854584693a9a0348fcdbaf9ee1351c5/WD-9-034-19-pdf-data.pdf> (last accessed: 17 December 2019).

25 See also in this regard the application situation; EU Commission, "Joint Assessments – Progress Report, Update – 2 October 2019", October 2019, p. 2, <https://ec.europa.eu/docsroom/documents/37383/attachments/1/translations/en/renditions/native>. Even this is a significant reduction as in 2012 there were about 80 notified bodies in Europe; see EU Commission, "Proposal for a Regulation on medical devices", 26 September 2012, p. 2, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012PC0542&from=EN> (last accessed: 17 December 2019).

26 See Art. 53 (1), sentence 1 Medical Devices Regulation. Information on the medical devices for which the relevant notified body is able to carry out conformity assessments is available from "Nando"; see for example EU Commission, "Notified bodies Nando", <https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notification.pdf&dir_id=34&ntf_id=301510> (last accessed: 17 December 2019).

27 Regarding the heavy workload see also Federal Government "Antwort auf Kleine Anfrage 'Auswirkungen der neuen Medizinprodukteverordnung auf kleine und mittlere Unternehmen'", 12 July 2019, BT-Drs. 19/11541, p. 5, 6 and 7, <http://dipbt.bundestag.de/dip21/btd/19/115/1911541.pdf> (last accessed: 17 December 2019).

28 See e.g. Research Service of the German Bundestag, "Marktzugangsvoraussetzungen für Medizinprodukte in der EU nach derzeitiger und künftiger Rechtslage", 2019, p. 11, <https://www.bundestag.de/resource/blob/651548/d854584693a9a0348fcdbaf9ee1351c5/WD-9-034-19-pdf-data.pdf> (last accessed: 17 December 2019).

29 Generally on this see also: German Federal Ministry of Health, "Medizinprodukte, Nationaler Arbeitskreis (NAKI)", <https://www.bundesgesundheitsministerium.de/naki.html> (last accessed: 17 December 2019).

alia manufacturers of medical devices to meet their obligations: Thus, the date for the European database on medical devices (Eudamed) to become fully functional, which was planned for 26 May 2020, has been postponed until May 2022.[30] In addition, the effect of increased waiting time, with regard to the conformity assessment procedures by notified bodies, will be detrimental to innovation, at least in the short term, and may lead to disruption in supply. None of this is consistent with the original objectives of the Regulation which aim to guarantee patient safety and promote innovation.

A particular challenge is presented by class I medical devices for which the manufacturer has previously been able to carry out the conformity assessment itself, without the involvement of a notified body[31], but which do now require the involvement of a notified body.[32] This concerns e.g. re-usable surgical instruments.[33] The Regulation has not so far specified any transitional provisions for such medical devices.[34] This means that, as of 26 May 2020, these medical devices cannot be sold or used in medical care without authorisation from a notified body established under the new law. Thus, the new requirement for the involvement of a notified body is precisely what will hamper the supply of re-usable surgical instruments. Since these are instruments that are essential in everyday medical care, there is likely to be a reduction in quality of care.

In view of the particularly burdensome problem of class I products, the new transitional provision is necessary. This was also recognised by the Council which proposed a "corrigendum" to the Medical Devices Regulation.

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[30] See Art. 123 (3) (d) Medical Devices Regulation and EU Commission, "European database on medical devices (EUDAMED)", <https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/eudamed_en> (last accessed: 17 December 2019).

[31] See Research Service of the German Bundestag, "Marktzugangsvoraussetzungen für Medizinprodukte in der EU nach derzeitiger und künftiger Rechtslage", 2019, p. 7, <https://www.bundestag.de/resource/blob/651548/d854584693a9a0348fcdbaf9ee1351c5/WD-9-034-19-pdf-data.pdf> (last accessed: 17 December 2019).

[32] See Art. 52 (7) Medical Devices Regulation. See also the summary in Federal Government "Antwort auf Kleine Anfrage 'Auswirkungen der neuen Medizinprodukteverordnung auf kleine und mittlere Unternehmen'", 12 July 2019, BT-Drs. 19/11541, p. 4 and Annex, <http://dipbt.bundestag.de/dip21/btd/19/115/1911541.pdf> (last accessed: 17 December 2019).

[33] Also referred to as class "Ir"; see on this the Medical Device Coordination Group, "Draft: Guidance Notes for Manufacturers of Class I Medical Devices", 2019, p. 3 and 5, <https://www.bvmed.de/download/medical-device-class-1-entwurf-selbstzeritifizierung-englisch> (last accessed: 17 December 2019). See also Art. 52 (7) (c) and Annex VIII, No. 5.2, Rule 6, dash 2 Medical Devices Regulation. Example: scalpels.

[34] See also Irish and German Delegations, "Medical devices: Implementation of Regulation (EU) 2017/745 on medical devices (MDR)", June 2019, p. 3, <https://data.consilium.europa.eu/doc/document/ST-9774-2019-INIT/en/pdf> and Federal Government, "Antwort auf Kleine Anfrage ‚Auswirkungen der neuen Medizinprodukteverordnung auf kleine und mittlere Unternehmen'", 12 July 2019, BT-Drs. 19/11541, p. 7, <http://dipbt.bundestag.de/dip21/btd/19/115/1911541.pdf> (last accessed: 17 December 2019).

5 "Corrigendum" to the Medical Devices Regulation

Regulations must be translated concurrently into all official languages of the EU. This often takes place under considerable time pressure which may give rise to e.g. errors in individual language versions. A "correction" – a "corrigendum" – allows for obvious errors in an individual language version to be corrected in the relevant legal act following publication. Such a corrigendum is justified where it enables an erroneous language version to be brought back into line with the actual enactment passed by the European legislator.[35] Corrigenda are published in the Official Journal of the EU.[36]

There is no special legal basis in the European treaties for the corrigendum of a Regulation. Even corrigenda that have already been carried out do not refer to any legal basis but simply contain a list of the provisions to be corrected in the corresponding legal act.[37]

Even the Council's Rules of Procedure (hereinafter Council RP)[38] do not contain any procedural legal basis for making corrections. Instead, this corrigendum of the Medical Devices Regulation is based on Council minutes dating from 1975 in which a "procedure" for making corrections is described in only very general terms.[39] It does not form part of the Council RP. With regard to the Rule of Law, however, the legislative process must follow precisely defined rules which should be codified at the highest level, in this case in the European treaties. At the very least, they must be set down in the Rules of Procedure of the EU institutions, which is not the case for the aforementioned "procedure". The correction of the Medical Devices Regulation proposed by the Council has no adequate legal basis.

By contrast with the Council RP, the Rules of Procedure of the European Parliament[40] (hereinafter EP RP) contain rules on making corrigenda which specify the following procedure:[41] If an error is identified in a text adopted by Parliament and agreed with other EU institutions, the President of the Parliament seeks an agreement with these institutions on the necessary corrections. A draft corrigendum is then sent to the responsible parliamentary committee. The committee examines the draft and submits it to Parliament if it is satisfied that an error has occurred which can be corrected in the proposed manner. Insofar as the method of a corrigendum is supported by the parliamentary committee, the corrigendum will be announced at the following session of the EP. It is deemed to have been approved unless, not later than 24 hours after its announcement, a request is made by a political group or at least 38 MEPs[42] to put it to the vote. If the corrigendum is not approved, it is referred back to the responsible parliamentary committee. The latter may propose an amended corrigendum or close the procedure.

The change being made to the transitional provisions in the Medical Devices Regulation is not this type of corrigendum. It does not aim to correct typing or printing errors, errors of sequencing, editorial mistakes or

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35 See also Bobek, M. (2009), "Corrigenda in the Official Journal of the European Union: Community law as quicksand", European Law Review, Vol. 34, p. 950 et seq. and p. 957.

36 See also Bobek, M. (2009), "Corrigenda in the Official Journal of the European Union: Community law as quicksand", European Law Review, Vol. 34, p. 951. See also Art. 241 No. 5, sentence 1 Rules of Procedure of the European Parliament.

37 See e.g. the corrigendum of the Medical Devices Regulation of 3 May 2019, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745R(01)&from=EN> (last accessed: 17 December 2019).

38 Council of the European Union, Rules of Procedure, "Council's Rules of Procedure", p. 83 et seq., <https://www.consilium.europa.eu/media/29824/qc0415692enn.pdf> (last accessed: 17 December 2019).

39 See Council of the European Union "Corrigendum", 25 November 2019, p. 1, <https://data.consilium.europa.eu/doc/document/ST-13081-2019-INIT/en/pdf> (last accessed: 17 December 2019).

40 The current Rules of Procedure (2019-2024) are available at <http://www.europarl.europa.eu/doceo/document/RULES-9-2019-07-02_EN.pdf> (last accessed: 17 December 2019).

41 For full details on this see Art. 241 EP RP.

42 The so-called "low threshold" within the meaning of Art. 179 No. 1 (a) EP RP: one-twentieth of Parliament's Members (currently 751).

such like, nor does it correct any error in translation. The corrigendum in this case aims to effect a significant substantive change to the wording of a law after its official publication. The wording of the Regulation has been in place since its promulgation two and half years ago. Errors of law or motive on the part of the legislator cannot be "repaired" in this sort of expedited procedure.

Significant changes to the wording of the Medical Devices Regulation through a corrigendum should be ruled out on the basis of legal doctrine. Instead of a corrigendum, the parliamentary committee may come to the conclusion that a formal legislative proposal by the EU Commission is in fact the right approach. It cannot be ruled out that, due to the approach chosen by the Council, the planned changes will come under attack and be repealed in court - e.g. by way of an action for annulment [Art. 263 TFEU] brought by a Member State. This would give rise to further legal uncertainty and more negative consequences for all concerned.

Such changes to the law are only possible by way of an amending Regulation which must pass through the legislative process.[43] The ordinary legislative procedure will not prevent the timely adoption of an amending Regulation if the three institutions involved in the legislative process - EU Commission, European Parliament and the Council - work together. The fact that this can take place within a very tight time frame has been shown e.g. by the amendment to the Regulation establishing technical and business requirements for credit transfers and direct debits in euro [(EU) No. 260/2012]: In order to realise the Single Euro Payments Area (SEPA), all domestic and intra-European bank transfers and direct debits in euro, over the entire eurozone, had to be converted to SEPA transfers and direct debits by 1 February 2014. It became apparent that the conversion would not be fully completed by the cut-off date and that the resulting problems in making payments would lead to corresponding payment arrears and disruption to the market.[44] The ordinary legislative procedure that was then initiated - including publication of the amending Regulation in the Official Journal of the EU - was completed in three months.[45]

There is still enough time if the three-month schedule realised in 2014, is also met in this case. For this, however, the EU Commission must act now and initiate the legislative procedure in January 2020 at the latest in order to dispel legal uncertainty. The European legislator should pass such an amending Regulation by way of the urgency procedure.[46]

[43] Thus also Bobek, M. (2009), "Corrigenda in the Official Journal of the European Union: Community law as quicksand", European Law Review, Vol. 34, p. 951.

[44] See EU Commission, "Proposal for a Regulation amending Regulation (EU) No. 260/2012", p. 2, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013PC0937&from=EN> (last accessed: 17 December 2019).

[45] The procedure began on 9 January 2014 and ended with publication on 20 March 2014; for details see: <https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2013/0449(COD)&l=en> (last accessed: 17 December 2019).

[46] In principle, the following also applies: As of the date of application of the Medical Devices Regulation (26 May 2020), any responsible national authority may, under Art. 59 Medical Devices Regulation, authorise the placing on the market or putting into service of a medical device, without its having gone through the conformity assessment procedure, if its use is in the interest of public health or patient safety.