**ACT**

of 2026

**amending Act No 375/2022 on medical devices and in vitro diagnostic medical devices, as amended**

Parliament has adopted the following Act of the Czech Republic:

Article I

Act No 375/2022 on medical devices and in vitro diagnostic medical devices, as amended by Act No 241/2024, Act No 218/2025 and Act No 236/2025, is amended as follows:

1. At the end § 4(h), the word ‘and’ is replaced by a semicolon.

2. At the end of §4(i), the full stop is replaced by the word‘; and’ and the following subparagraph (j) is added:

‘j) issues or revokes measures of a general nature pursuant to § 53a.’.

3. At the end of § 5(2)(v), the word ‘and’ is replaced by a semicolon.

4. At the end of § 5(2), the full stop is replaced by a semicolon and the following subparagraphs (x) to (z) are added:

‘x) receives, collects, investigates and assesses information on impending shortages of devices from manufacturers in pursuant to § 8a and 8b, and data from distributors and importers pursuant to § 27a and from healthcare providers pursuant to § 39a;

y) informs the competent authorities of the other Member States and the Commission without undue delay of any anticipated interruption or cessation of supply of a device pursuant to Article 10a(2) of the Medical Devices Regulation or Article 10a(2) of the In Vitro Diagnostic Medical Devices Regulation; and

z) proposes to the Ministry the issuance or revocation of measures of a general nature pursuant to § 53a.’.

5. After § 8, the following new § 8a and § 8b are inserted, including headings:

‘§ 8a

**Obligations of manufacturers in the event of a interruption or cessation of supply of a device**

(1) A manufacturer established in the Czech Republic or whose authorised representative is established in the Czech Republic provides information to the Institute on the expected interruption or cessation of supply of a device pursuant to Article 10a(1) of the Medical Devices Regulation or Article 10a(1) of the In Vitro Diagnostic Medical Devices Regulation by means of an electronic report. The information to be included in the report pursuant to the

first sentence to the extent of device identification data and related data on the anticipated interruption or cessation of supplies provided pursuant to the first sentence is laid down in implementing legislation.

(2) A manufacturer established in the Czech Republic or whose authorised representative is established in the Czech Republic provides the information pursuant to paragraph (1) via a form published on the Institute's website.

(3) The Ministry shall announce the date on which the part of the Medical Devices Information System that provides information on the anticipated interruption or cessation of supply of a device pursuant to Article 10a(1) of the Medical Devices Regulation or Article 10a(1) of the In Vitro Diagnostic Medical Devices Regulation became operational no later than 30 days after it becomes operational by means of a communication in the Collection of Legislative Acts and International Treaties.

§ 8b

**Obligations of manufacturers in the event of an investigation of device availability**

A manufacturer established in the Czech Republic, or whose authorised representative is established in the Czech Republic, shall, upon request by the Institute, provide the information necessary to investigate and assess the unavailability of a device essential for the provision of healthcare services, or the information necessary to assess the justification for the continued application of a measure of a general nature issued pursuant to § 53a(3); the manufacturer shall provide this information to the Institute by the deadline stipulated in the request.'.

6. § 8a(2) reads as follows:

'(2) The information pursuant to paragraph (1) is provided to the Institute through the Medical Device Information System.'.

7. After § 27 the following new § 27a is inserted, including the heading:

'§ 27a

**Obligations of distributors and importers in the event of an investigation of device availability**

Upon request by the Institute, a distributor or importer shall provide the information necessary to investigate and assess the unavailability of a device essential for the provision of healthcare services, or the information necessary to assess the justification for the continued application of a measure of a general nature issued pursuant to § 53a(3); the healthcare provider shall provide this information to the Institute by the deadline stipulated in the request.'.

8. After § 39 the following new § 39a is inserted, including the heading:

‘§ 39a

**Obligations of healthcare providers in the event of an investigation of device availability**

Upon request by the Institute, a healthcare provider shall provide the information necessary to investigate and assess the unavailability of a device essential for the provision of healthcare services, or the information necessary to assess the justification for the continued application of a measure of a general nature issued pursuant to § 53a(3); the healthcare provider shall provide this information to the Institute by the deadline stipulated in the request.’.

9. After § 53 the following new § 53a is inserted, including the heading:

‘§ 53a

**Measures to ensure device availability**

l) The Institute investigates and assesses the availability of devices essential for the provision of healthcare services. If, on the basis of information and data obtained during the investigation, the Institute concludes that the availability of a device essential for the provision of healthcare services is at risk, and that a shortage of this device will jeopardise the availability of healthcare for patients in the Czech Republic, thereby affecting the protection of public health, it shall propose to the Ministry the issuance of a measure of a general nature and shall provide it with the supporting documentation justifying the proposal, on the basis of which it reached this conclusion. In the supporting documents pursuant to the second sentence, the Institute shall propose amendment of conditions for

m) placing the device on the market;
n) supplying the device to the market;
o) putting the device into operation; or
p) prescribing, dispensing or using the device in the provision of health services.

(2) In carrying out the investigation pursuant to paragraph (1), the Institute shall evaluate, in particular, the information and data obtained

a) pursuant to § 8a(1);
b) based on requests pursuant to § 8b, § 27a or § 39a;
c) from other Member States pursuant to Article 10a of the Medical Devices Regulation or Article 10a of the In Vitro Diagnostic Medical Devices Regulation;
d) based on its own market monitoring or investigations.

(3) Taking into account the information, data and supporting documents pursuant to paragraphs (1) and (2), the Ministry may, by means of a measure of general nature, temporarily amend the conditions for the placing on the market, supply to the market, putting into service, prescribing, dispensing or use of a device in the provision of healthcare services; this is without prejudice to the rules on the placing on the market and supply of the device or putting it into service pursuant to the Medical Devices Regulation or the In Vitro Diagnostic Medical Devices Regulation.

(4) The Ministry issues measures of a general nature without a consultation process. A measure of a general nature takes effect on the date specified therein and is published by way of a public notice on the Ministry’s electronic bulletin board.

(5) In the course of its official duties and on the basis of the information and data obtained in accordance with paragraph (2), the Institute assesses the availability of a device for which a measure of a general nature was issued and, at least once every three months, reviews the need for the measure of a general nature to remain in effect. If the Institute concludes that the reasons for issuing a measure of a general nature have changed or ceased to exist, it shall communicate this information to the Ministry, including the data on the basis of which it came to this conclusion.

(6) If, taking into account the information pursuant to paragraph (5), the Ministry concludes that the grounds for issuing the measure of a general nature have changed or ceased to exist, it shall revoke the measure of a general nature. In the event of a change in the grounds for the adoption of a measure of a general nature, together with the revocation of the measure of a general nature pursuant to the first sentence, the Ministry shall issue a new measure of a general nature in which it shall take this change into account.'.

10. At the end of § 55(2)(p), the word 'or' is deleted.

11. At the end of § 55(2), the full stop is replaced by a semicolon and the following points (t) to (v) are added:

'(r) contrary to Article 10a(1) of the Medical Devices Regulation or contrary to Article 10a(1) of the In Vitro Diagnostic Medical Devices Regulation, or contrary to § 8a(1), failing to inform the Institute of an anticipated interruption or cessation of supply of a device;

s) contrary to Article 10a(1) of the Medical Devices Regulation or contrary to Article 10a(1) of the In Vitro Diagnostic Medical Devices Regulation, failing to inform any of the economic operator pursuant to Article 2(35) of the Medical Devices Regulation or Article 2(28) of the In Vitro Diagnostic Medical Devices Regulation, or any healthcare provider, of the intended interruption or cessation of supply of a device that it supplies directly to them;

t) providing the Institute with information regarding any anticipated interruption or cessation of supply of a device, but not to the extent pursuant to implementing legislation issued based on § 8a(1);

u) failing to provide the Institute with the information pursuant to § 8b upon request; or

v) failing to comply with any of the conditions for placing a device on the market or putting it into service laid down by a measure of a general nature issued based on § 53a(3).'.

12. In § 55(5)(d), the words 'or (m),' are replaced by ', (m), (s), (t), (u) or (v),'.

13. In § 55(5)(e), the words 'or (o)' are replaced by the words '(o) or (p)'.

14. At the end of § 57(1)(s), the word 'or' is deleted.

15. At the end of § 57(1), the full stop is replaced by a semicolon and the following subparagraphs (u) to (w) are added:

‘u) contrary to Article 10a(3) of the Medical Devices Regulation or contrary to Article 10a(3) of the In Vitro Diagnostic Medical Devices Regulation, failing to inform any of the economic operators pursuant to Article 2(35) of the Medical Devices Regulation or Article 2(28) of the In Vitro Diagnostic Medical Devices Regulation or any of the health service providers to whom it directly supplies the device without undue delay of any foreseen interruption or cessation of supply of the device, although it has been informed by a manufacturer or other economic operator pursuant to Article 2(35) of the Medical Devices Regulation or Article 2(28) of the In Vitro Diagnostic Medical Devices Regulation in the supply chain of the interruption or cessation of supply;

v) failing to provide the Institute with the information pursuant to § 27a upon request; or

w) failing to comply with any of the conditions for placing a device on the market or putting it into service laid down by a measure of a general nature issued based on § 53a(3).’.

16. In § 57(2)(d), the words ‘or (m)’ is replaced by ‘, (m), (u), (v) or (w)’.

17. At the end of § 58(1)(s), the word ‘or’ is deleted.

18. At the end of § 58(1), the full stop is replaced by a semicolon and the following subparagraphs (o) to (q)
are added:

‘o) contrary to Article 10a(3) of the Medical Devices Regulation or contrary to Article 10a(3) of the In Vitro Diagnostic Medical Devices Regulation, failing to inform any of the economic operators pursuant to Article 2(35) of the Medical Devices Regulation or Article 2(28) of the In Vitro Diagnostic Medical Devices Regulation or any of the health service providers to whom it directly supplies the device without undue delay of any foreseen interruption or cessation of supply of the device, although it has been informed by a manufacturer or other economic operator pursuant to Article 2(35) of the Medical Devices Regulation or Article 2(28) of the In Vitro Diagnostic Medical Devices Regulation in the supply chain of the interruption or cessation of supply;

p) failing to provide the Institute with the information pursuant to § 27a upon request; or

q) breaching any of the conditions for placing the device on the market or putting it into service laid down in a measure of general application issued pursuant to § 53a(3).’.

19. In § 58(2)(c), the words ‘or (l);’ are replaced by the words ‘, (l), (o), (p) or (q);’.

20. At the end § 59(1)(g), the word ‘or’ is deleted.

21. At the end of § 59(1), the full stop is replaced by a semicolon and the following subparagraphs (i) and (j) are added:

‘i) failing to provide the Institute with the information pursuant to § 39a upon request; or

j) failing to comply with any of the conditions for use of a device laid down by a measure of a general nature issued based on § 53a(3).'.

22. In § 59(3)(c), the words 'or (g),' are replaced by the words ', (g), (i) or (j),'.

23. At the end § 60(1)(i), the word 'or' is deleted.

24. At the end of § 60(1), the full stop is replaced by the word '; or' and the following subparagraph
(k) is added:

'k) breaching any of the conditions for dispensing the device laid down by a measure of a general nature issued based on § 53a(3).'.

25. In § 60(2)(c), the words 'or (j)' are replaced by the words ', (j) or (k)'.

26. § 61(4) reads as follows:

'(4) Prescribers commit an infraction by
a) prescribing a device to a patient on a paper prescription contrary to § 28a;
b) contrary to § 29(4), providing a patient with an electronic prescription identifier in return for payment; or
c) failing to comply with any of the conditions for prescribing a device laid down by a measure of a general nature issued pursuant to § 53a(3).'.

27. In § 68, the words '§ 8a(1),' are inserted after the words 'for the implementation of'.

Article II

**Technical regulation**

This Act was notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Article III

**Effective date**

This Act comes into effect on the day following the date of its publication, with the exception of the provisions of Article I(6), which come into effect on the first day of the third calendar month following the date indicated as the date on which the part of the Medical Devices Information System which provides information on the anticipated interruption or cessation of supply of a device is made available in a communication from the Ministry of Health published in the Collection of Legislative Acts and International Agreements.