Council of the European Union

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**'I' ITEM NOTE**

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| Subject: | Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices **(first reading)**<br>- Preparation for adoption of the legislative act |

1. On 15 October 2021 the Commission sent its proposal[1], based on Articles 114 and 168(4) TFEU, to the Council.

2. The European Economic and Social Committee delivered its opinion on 8 December 2021[2].

3. The European Committee of the Regions was consulted and decided not to give an opinion.

4. Informal contacts were undertaken between the Council, the European Parliament and the Commission with the aim of reaching agreement at first reading.

[1] 12884/21
[2] Not yet published in the OJ.

5. On 24 November 2021, the Permanent Representatives Committee endorsed the agreement reached with the European Parliament and authorised the Chair to send a letter to the Chair of the ENVI Committee stating that should the European Parliament adopt its position at first reading in the form set out in that letter, subject to revision by the legal linguists of both institutions, the Council would approve the European Parliament's position and the act shall be adopted in the wording which corresponds to the European Parliament's position.

6. The European Parliament will adopt its position at first reading at its plenary on 13-16 December 2021.

7. The Permanent Representatives Committee is therefore invited to agree that, should the European Parliament adopt its position at first reading in the form set out in the letter to the Chair of the ENVI Committee referred to in paragraph 5 of this note, as revised by the legal linguists of both institutions in PE-CONS 79/21[3], the Council would be invited to approve the European Parliament's position as an "A" item at a forthcoming meeting.

8. At the same time, the Permanent Representatives Committee is invited to decide, in accordance with the first subparagraph of Article 12(1) of the Council's Rules of Procedure and Article 1 of Council Decision (EU) 2021/2098[4], that the Council uses the written procedure for the approval of the European Parliament's position at the first reading, provided that that position is in the form set out in the letter to the Chair of the ENVI Committee referred to in paragraph 5 of this note and that no Council meeting with quorum takes place before 21 December 2021.

9. If the Council approves the European Parliament's position, the act shall be adopted in the wording, which corresponds to the European Parliament's position.

   After being signed by the President of the European Parliament and the President of the Council, the legislative act will be published in the *Official Journal of the European Union*.

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[3] Available on 17.12.2021.

[4] Council Decision (EU) 2021/2098 of 25 November 2021 further extending the temporary derogation from the Council's Rules of Procedure introduced by Decision (EU) 2020/430, in view of the travel difficulties caused by the COVID-19 pandemic in the Union (OJ L 427, 30.11.2021, p. 194–195).