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INFORMATION NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: **ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING**
Proposal for a Regulation of the European Parliament and of the Council on Medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
– Outcome of the European Parliament's second reading (Strasbourg, 3 to 6 April 2017)

I. VOTE

Since no amendment had been adopted, the President of the European Parliament declared the Council's position at first reading approved.

The text of the European Parliament's legislative resolution is annexed to this note.

II. ADOPTION OF LEGISLATIVE ACTS FOLLOWING THE EUROPEAN PARLIAMENT'S SECOND READING

Since the European Parliament has approved the Council's position at first reading, the act in question is deemed to have been adopted in the wording which corresponds to the Council's position at first reading, as provided for in Article 294 (7)(a) of the TFEU.

After signature by the President of the European Parliament, the President of the Council and the Secretaries-General of the two Institutions, the act in question will be published in the *Official Journal* of the European Union.

Medical devices ***II

European Parliament legislative resolution of 5 April 2017 on the Council position at first reading with a view to the adoption of a regulation of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (10728/4/2016 – C8-0104/2017 – 2012/0266(COD))

(Ordinary legislative procedure: second reading)

The European Parliament,

- having regard to the Council position at first reading (10728/4/2016 – C8-0104/2017),
 - having regard to the opinion of the European Economic and Social Committee of 14 February 2013¹,
 - having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2012)0542),
 - having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 67a of its Rules of Procedure,
 - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A8-0068/2017),
1. Approves the Council position at first reading;
 2. Notes that the act is adopted in accordance with the Council position;
 3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;

¹ OJ C 133, 9.5.2013, p. 52.

² Texts adopted: P7_TA(2014)0266.

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;
 5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.
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