



Council of the
European Union

**Brussels, 16 May 2022
(OR. en)**

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	12 May 2022
To:	General Secretariat of the Council
No. Cion doc.:	C(2022) 3041 final - Annex
Subject:	ANNEX to Commission Delegated Directive amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in certain magnetic resonance imaging devices

Delegations will find attached document C(2022) 3041 final - Annex.

Encl.: C(2022) 3041 final - Annex



Brussels, 12.5.2022
C(2022) 3041 final

ANNEX

ANNEX

to

Commission Delegated Directive

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of lead in certain magnetic resonance imaging devices

ANNEX

In Annex IV to Directive 2011/65/EU, in entry 27, the following points (c) and (d) are added:

	<p>(c) MRI non-integrated coils, for which the Declaration of Conformity of this model is issued for the first time before [PO: the date of publication in the Official Journal of the Delegated Directive + 1 day], or</p> <p>(d) MRI devices including integrated coils, which are used in magnetic fields within the sphere of 1 m radius around the isocentre of the magnet in medical magnetic resonance imaging equipment, for which the Declaration of Conformity is issued for the first time before 30 June 2024.</p> <p>Expires on 30 June 2027.’</p>
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