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European Union

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| From: | Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director |
| date of receipt: | 13 March 2019 |
| To: | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |

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| No. Cion doc.: | C(2019) 1789 final - Annex 5 |
| Subject: | ANNEX to the Commission Delegated Regulation supplementing Directive 2010/40/EU of the European Parliament and of the Council with regard to the deployment and operational use of cooperative intelligent transport systems |

Delegations will find attached document C(2019) 1789 final - Annex 5.

Encl.: C(2019) 1789 final - Annex 5



Brussels, 13.3.2019
C(2019) 1789 final

ANNEX 5

ANNEX

to the

Commission Delegated Regulation

**supplementing Directive 2010/40/EU of the European Parliament and of the Council
with regard to the deployment and operational use of cooperative intelligent transport
systems**

{SEC(2019) 100 final} - {SWD(2019) 95 final} - {SWD(2019) 96 final}

ANNEX V

PART A

CONFORMITY ASSESSMENT PROCEDURES

Module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on its sole responsibility that the C-ITS stations concerned satisfy the requirements of this Regulation that apply to them.

2. Technical documentation

The manufacturer shall establish technical documentation enabling assessment of the C-ITS station's conformity with the relevant requirements and including an adequate analysis and assessment of the risk(s). The documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. As applicable, it shall contain at least:

- a general description of the C-ITS station;
- conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits, etc.;
- descriptions and explanations as required for the understanding of those drawings and schemes, and the operation of the C-ITS station;
- a list of harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union* or international standards, applied in full or in part, and descriptions of the solutions adopted to comply with this Regulation where such harmonised standards have not been applied. Where harmonised standards have been applied in part, the technical documentation shall specify which parts have been applied;
- results of design calculations, examinations, etc.; and
- test reports.

3. Manufacturing

The manufacturer shall take all necessary measures to ensure that the manufacturing process and its monitoring guarantee that the C-ITS stations comply with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Conformity marking and declaration of conformity

4.1. The manufacturer shall affix the conformity marking required by this Regulation to each individual C-ITS station that satisfies the applicable requirements of this Regulation.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The

declaration of conformity shall identify the C-ITS station for which it has been drawn up.

A copy of the declaration shall be made available to the relevant authorities on request.

5. **Authorised representative**

The manufacturer's obligations, as set out in point 4, may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

PART B

EC DECLARATION OF CONFORMITY

1. No (unique identification of the C-ITS station): ...
2. Name and address of the manufacturer or its authorised representative: ...
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer): ...
4. Object of the declaration (identification of the C-ITS station allowing traceability; this may include a photograph, where appropriate): ...
5. The object of this declaration is in conformity with the relevant Union harmonisation legislation: ...
6. References to the relevant harmonised standards used or references to the other specifications in relation to which conformity is declared: ...
8. Additional information: ...

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)

PART C

CENTRAL C-ITS STATIONS: CONFORMITY ASSESSMENT PROCEDURES

Module A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the operator fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on its sole responsibility that the central C-ITS stations concerned satisfy the requirements of this Regulation that apply to them.
2. **Technical documentation**

The operator shall establish technical documentation enabling assessment of the central C-ITS station's conformity with the relevant requirements and including an adequate analysis and assessment of the risk(s). The documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. As applicable, it shall contain at least:

 - a general description of the central C-ITS station;
 - conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits, etc.;
 - descriptions and explanations as required for the understanding of those drawings and schemes, and the operation of the central C-ITS station;
 - a list of harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union* or international standards, applied in full or in part, and descriptions of the solutions adopted to comply with this Regulation where such harmonised standards have not been applied. Where harmonised standards have been applied in part, the technical documentation shall specify which parts have been applied;
 - results of design calculations, examinations, etc.; and
 - test reports.
4. **Declaration of conformity**

The operator shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities as long as the central C-ITS station is in operation. The declaration of conformity shall identify the central C-ITS station for which it has been drawn up.

A copy of the declaration shall be made available to the relevant authorities on request.
5. **Authorised representative**

The operator's obligations, as set out in point 4, may be fulfilled by its authorised representative, on its behalf and under its responsibility, provided that they are specified in the mandate.

PART D

CENTRAL C-ITS STATIONS: EC DECLARATION OF CONFORMITY

1. No (unique identification of the C-ITS station): ...
2. Name and address of the operator or its authorised representative: ...
3. This declaration of conformity is issued under the sole responsibility of the operator:
...
4. Object of the declaration (identification of the central C-ITS station allowing traceability): ...
5. The object of this declaration is in conformity with the relevant Union harmonisation legislation: ...
6. References to the relevant harmonised standards used or references to the other specifications in relation to which conformity is declared: ...
8. Additional information: ...

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)
