

MDCG 2020-2

Class I Transitional provisions under Article 120 (3 and 4) – (MDR)

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How can affected manufacturers of some class I devices¹ make efficient use of the transitional provisions in Article 120 (3) and (4) of Regulation (EU) 2017/745 – Medical Devices Regulation (MDR)?

Background:

The corrected MDR² Article 120 (3) allows under certain conditions, some class I devices pursuant to Directive 93/42/EEC – Medical Devices Directive (MDD), for which the Declaration of Conformity was drawn up **prior to 26 May 2020** and for which the conformity assessment procedure pursuant to the MDR would require the involvement of a notified body, to be placed on the market³ **until 26 May 2024**⁴.

In order to make use of this article, the following conditions must be met:

1. The device continues to comply with Directive 93/42/EEC,
2. A notified body will need to be involved under the MDR (e.g. re-usable surgical instruments or up-classified devices)
3. A valid Declaration of Conformity, according to Annex VII of the MDD, must be drawn up **before 26 May 2020**,
4. No significant changes to the design or intended purpose of the device after 26 May 2020⁵,
5. The requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in Directive 93/42/EEC.⁶ This shall be in place on the 26 May 2020.

Scope

The scope of this document is to provide guidance related to the information to be provided in the form of a Declaration of Conformity by manufacturers of Class I devices (devices which are non-sterile or do not have a measuring function) that are required to have certificates after 26 May 2024 according to the MDR.

¹ Class I devices for which the conformity assessment procedure pursuant to the MDR would require the involvement of a notified body.

² Corrigendum to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 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 (OJ L 117, 5.5.2017), of 27.12.2019.

³ Devices which are not placed on the market but put into service may also make use of the transitional provisions.

⁴ Article 120(4) ‘and may continue to be made available on the market...until 27 May 2025’.

⁵ Guidance on significant changes under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.

⁶ Upcoming guidance on harmonised practices and technical solutions to facilitate exchange of information in absence of EUDAMED.

Content of a valid Declaration of Conformity

The manufacturer or his authorised representative established in the European Union is obliged to issue a Declaration of Conformity that the product has undergone a conformity assessment procedure required by the MDD before being placed on the market.

With the Declaration of Conformity, the manufacturer declares that the products concerned meet the relevant provisions of the MDD.

MDD Annex II, Annex V, Annex VI set out that a Declaration of Conformity must cover one or more medical devices manufactured ⁷ clearly identified by means of product name, product code or other unambiguous reference for class IIa, IIb and III devices, and also class Im and class Is devices. This is however not necessary for other Class I devices, as it is not required by the MDD (Annex VII) and as there is no certificate from a notified body to which the issued Declaration of Conformity is related.

Guidance on the content of the Declaration of Conformity can be found, inter alia, in the “**The ‘Blue Guide’ on the implementation of EU products rules 2016 (2016/C272/01)**”⁸ and the standard EN ISO/IEC 17050-1.⁹ According to this standard, the declaration may take the form of a document or any other suitable medium, and should contain sufficient information to enable all products covered to be traced back to it. The model declaration in Annex III of Decision No 768/2008/EC and the ‘Blue Guide’ on the implementation of EU products rules 2016 (2016/C272/01) describe the content of the Declaration of Conformity to be as follows:

1. A number identifying the product. This number does not need to be unique to each product. It could refer to a product, batch, type or a serial number.¹⁰ This is left to the discretion of the manufacturer.¹¹
2. The name and address of the manufacturer or the authorised representative issuing the declaration.
3. A statement that the declaration is issued under the sole responsibility of the manufacturer.
4. The identification of the product allowing traceability. This is any relevant information supplementary to point 1 describing the product and allowing for its traceability. Where relevant for the identification of the product, it may contain an image, but unless specified as a requirement in the Union harmonisation legislation this is left to the discretion of the manufacturer.

⁷ MDD Annex II, paragraph 2 ‘This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer.’

⁸ [https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52016XC0726\(02\)](https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:52016XC0726(02)).

⁹ EN ISO/IEC 17050-1 : 2004 Conformity assessment – Supplier’s Declaration of Conformity – Part 1: General requirements /EN ISO/IEC 17050-2 : 2004 Conformity assessment – Supplier’s Declaration of Conformity – Part 2: Supporting documentation.

¹⁰ The ‘number’ may be an alpha-numerical code or could also refer to a software version.

¹¹ In addition, whether this is expressly envisaged or not by the Union harmonisation legislation, manufacturers are free to add a number identifying the Declaration of Conformity itself in line with EN ISO/IEC 17050-2.

5. All relevant Union harmonisation legislation complied with; the referenced standards or other technical specifications (such as national technical standards and specifications) in a precise, complete and clearly defined way; this implies that the version and/or date of the relevant standard is specified.¹²
6. If applicable, the name and identification number of the notified body,¹³ when it has been involved in the conformity assessment procedure,^{14 15} and the reference to the relevant certificate.
7. If applicable, all supplementary information that may be required (for example category).
8. The date of issue of the declaration; signature and title or an equivalent marking of the authorised person^{16 17}
 - ✓ This could be any date after the completion of the conformity assessment, **but must be before 26 May 2020** if the manufacturer wants to make use of the transitional period in Article 120(3) and (4) of the MDR.

Every Declaration of Conformity must be based on proper technical documentation according to Annex VII paragraph 3 of the MDD. The technical documentation and the Declaration of Conformity should be subject to appropriate measures of document and record control. The Declaration of Conformity is to be kept by the manufacturer and shall be at the disposal of the competent authorities for a period ending at least five years after the last product has been manufactured.

Necessary amendments/updates to the technical documentation should be done in a transparent manner. Both the changes and the dates of when the changes were made should be recorded. On the basis of the Declaration of Conformity and the corresponding technical documentation, the manufacturer should be able to demonstrate that the Declaration of Conformity was lawfully¹⁸ issued **before 26 May 2020** and that, subsequently, there are no significant changes in the design or intended purpose¹⁹ in the meaning of Article 120(3) MDR. Taking into account Article 123(3) and 123 (3)(d), and as EUDAMED will not be fully functional in May 2020, it is required that the manufacturer keep the Declaration of Conformity together with the technical documentation available to the Competent Authorities. This would also include details of all device registrations and economic operator registrations completed pursuant to national provisions implementing the requirements of Articles 14 (1) and (2) of Directive 93/42/EEC.

¹² According to the MDD, referencing standards or technical specifications complied with is voluntary.

¹³ For class I devices in scope of this guidance document, the involvement of a notified body is not required.

¹⁴ Not all Union harmonisation legislation requires the intervention of a notified body (e.g. the Low Voltage Directive and the Toys Directive).

¹⁵ The name and address of the person who keeps the technical documentation may also be required by some pieces of Union harmonisation legislation since according to those, not only the manufacturer shall keep the technical documentation.

¹⁶ This could be the managing director of the company or another representative of the company to whom this responsibility has been delegated.

¹⁷ It is not necessary for the signatory to be domiciled in the European Union. A manufacturer established outside the Union is entitled to carry out all the conformity assessment procedures at his premises and, to sign the Declaration of Conformity.

¹⁸ Lawfully according to the Directive and to any relevant national provisions which apply.

¹⁹ Guidance on significant changes under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD.