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CLASS I MDD DEVICES BENEFITTING FROM ARTICLE 120 MDR

Preliminary Note re: Flowchart

Based on the analyses and conclusions contained in the present paper, we have drawn up a **separate flowchart** intended to provide simplified, easily accessible guidance for (potentially) affected manufacturers and other economic operators on the matters covered by this paper. Therefore, please refer to the flowchart for a «quick overview» and to the present paper for details on the individual steps contained therein.

The flowchart, as well as the present paper, are available at:

www.muresan.legal/ENGLISH/PUBLICATIONS/OP-MDR-120/

1 Background and Relevant Questions

The (partly amended) provisions of art. 120 pars. 3 and 4 MDR allow, under certain conditions, that some class I medical devices may be placed or made available on the market or be put into service until 26 May 2024, or 26 May 2025 respectively, i.e. for periods exceeding the date of application of the MDR (which is 26 May 2021). The MDCG has, in March 2020, issued a document (no. 2020-2; «Class I Transitional provisions under Article 120 (3 and 4) – (MDR)») aiming at providing guidance on how manufacturers of some of the devices concerned can make efficient use of the transitional periods provided for by art. 120 pars. 3 and 4 MDR. However, the information and representations contained in this document appear, in part, somewhat ambiguous and inconsistent. Against this backdrop, the present paper assesses the following two questions:

1) **Which medical devices may benefit from the transitional provision of art. 120 par. 3 MDR?**
2) **Under what conditions and/or requirements?**

These questions will be assessed below (see sections 3 and 4). First, however, the MDR provisions most relevant to that assessment shall be represented (section 2 below).

2 Most Relevant MDR Provisions

2.1 Article 120 par. 3, First Subparagraph

The MDR provision primarily relevant here is **art. 120 par. 3 (first subparagraph)**. It has, in its amended version, the following wording:

> «By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a Notified Body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.»

2.2 Article 120 par. 4

In addition, **art. 120 par. 4 MDR** is also relevant here. It has, in its amended version, the following wording:

> «Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2021, and devices placed on the market from 26 May 2021 pursuant to paragraph 3 of this Article, may continue to be made available on the market or put into service until 26 May 2025.»

2.3 Article 120 par. 2

Finally, **art. 120 par. 2 MDR** is also relevant. It has the following wording:

> «Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022.
>
> Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.»

3 As to Question 1 (Devices Covered)

3.1 Overview

There are **two categories of class I medical devices** that benefit from the (amended) transitional provision of art. 120 par. 3 MDR:

- **Class I devices not requiring NB involvement under the MDD** (see section 3.2 below) and
- **Class I devices requiring NB involvement already under the MDD** (see section 3.3 below).

These two categories differ with regard to the conditions and requirements that must be met in order for the medical devices concerned to benefit from art. 120 par. 3 MDR (as to the respective conditions and requirements, see section 4 below).

3.2 Class I Devices Not Requiring NB Involvement Under the MDD

This first category of devices that benefit from art. 120 par. 3 MDR encompasses the following medical devices:

GENERAL DESCRIPTION

- Devices which are class I devices pursuant to the MDD and
- which do *not* require, *under the MDD*, the involvement of a Notified Body *but*
- for which the conformity assessment procedure *under the MDR does* require the involvement of a Notified Body.

SPECIFICALLY:

- **Re-usable surgical instruments** (see art. 52 par. 7 MDR);
- **«Up-classified» MDD class I devices** (i.e., devices that are class I under the *MDD* but class IIa or higher under the *MDR*, e.g.: any substance-incorporating devices in class I under the MDD – these will be class III under the MDR; many software products);
- Devices regarding which Notified Bodies must be involved due to **art. 52 pars. 10 or 11 MDR**:
  - Class I devices manufactured utilising tissues or cells of animal or human origin, or their derivatives, which are non-viable or are rendered non-viable, and are devices intended to come into contact with intact skin only (see art. 52(10) in conjunction with art. 1(6)(f) and (g) MDR as well as Classification Rule 18);
  - Any class I device which, when placed on the market or put into service, incorporates, as an integral part, non-viable tissues or cells of human origin or their derivatives that have an action ancillary to that of the device (see art. 52(10) in conjunction with art. 1(10) MDR);
  - Class I devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body (see art. 52(11) MDR).

→ *As to the **conditions and requirements** that must be met in order for these devices to benefit from the transitional provision of art. 120 par. 3 MDR, **see section 4.1 below**.*

3.3 Class I Devices Requiring NB Involvement Already Under the MDD

The second category of devices that benefit from art. 120 par. 3 MDR encompasses the following devices:

GENERAL DESCRIPTION

- Devices which are class I devices pursuant to the MDD and
- which *do require*, *already under the MDD*, the involvement of a Notified Body.

SPECIFICALLY:

- Class I medical devices **placed on the market in sterile condition** (see annex VII, section 5, MDD);
- Class I medical devices **with a measuring function** (see annex VII, section 5, MDD).

→ *As to the **conditions and requirements** that must be met in order for these devices to benefit from the transitional provision of art. 120 par. 3 MDR, **see section 4.2 below**.*

4 As to Question 2 (Conditions and Requirements)

4.1 Class I Devices Not Requiring NB Involvement Under the MDD

CONDITIONS & REQUIREMENTS

With regard to class I devices not requiring involvement of a Notified Body under the MDD (see section 3.2 above), the following conditions and requirements must be met:

- The **Declaration of Conformity** must be, or must have been, issued **prior to 26 May 2021**.
  - → With regard to the specific **contents** of the Declaration of Conformity, see the guidance provided in the MDCG document 2020-2, pages 3-4.
- The requirements specified in art. 120 par. 3, last sentence, MDR must be complied with, which means that:
  - **Post-market surveillance** must be carried out in accordance with Chapter VII, Section 1, of the *MDR*;
  - **Market surveillance** must be carried out in accordance with Chapter VII, Section 3, of the *MDR*;
  - **Vigilance** must be carried out in accordance with Chapter VII, Section 2, of the *MDR*;
  - **Economic operators** and the **medical devices** concerned must be **registered** in accordance with articles 29 et seqq. of the *MDR*.
- The **remaining requirements resulting from the MDD** must continue to be complied with beyond 26 May 2021.
- **No significant changes in the design and intended purpose of the device** may be made at any time.
  - → With regard to the circumstances under which such changes may be considered **«significant»**, see the guidance provided in the MDCG document 2020-3 («Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD»).

EFFECTS / CONSEQUENCES

If all of the conditions and requirements specified above are met with regard to a particular device, the device concerned **may be placed on the market or put into service also after 26 May 2021**, without having to comply with any further requirements (in particular, **without having to involve a Notified Body** in the conformity assessment, despite the fact that this would be required by the MDR from 26 May 2021 on).

However, such devices may only be **placed on the market until 26 May 2024** (art. 120 par. 3 MDR), and they may only continue to be **made available on the market** or **put into service until 26 May 2025** (art. 120 par. 4 MDR).

4.2 Class I Devices Requiring NB Involvement Already Under the MDD

CONDITIONS & REQUIREMENTS

With regard to class I devices already requiring involvement of a Notified Body under the MDD (see section 3.3 above), the following conditions and requirements must be met:

- The **certificate** issued by the NB must be, or must have been, issued **in accordance with the MDD**.
- The certificate issued by the Notified Body must be valid by virtue of art. 120 par. 2 MDR:
  - **Certificates issued prior to 25 May 2017** are valid until the **end of the period indicated on the certificate**;
  - **Certificates issued prior to 25 May 2017 in accordance with annex IV to the MDD** (EU verification procedure) are, in any event, only valid until **26 May 2022** at longest;
  - **Certificates issued from 25 May 2017** are valid until the **end of the period indicated on the certificate** (which may not exceed five years from its issuance) but, in any event, until **26 May 2024** at longest.
- The **Declaration of Conformity** must be issued or updated in accordance with the certificate issued by the Notified Body.
  → With regard to the specific **contents** of the Declaration of Conformity, see the guidance provided in the MDCG document 2020-2, pages 3-4.
- The requirements specified in art. 120 par. 3, last sentence, MDR must be complied with, which means:
  - **Post-market surveillance** must be carried out in accordance with Chapter VII, Section 1, of the *MDR*;
  - **Market surveillance** must be carried out in accordance with Chapter VII, Section 3, of the *MDR*;
  - **Vigilance** must be carried out in accordance with Chapter VII, Section 2, of the *MDR*;
  - **Economic operators** and the **medical devices** concerned must be **registered** in accordance with articles 29 et seqq. of the *MDR*.
- The **remaining requirements resulting from the MDD** must be complied with beyond 26 May 2021.
- **No significant changes in the design and intended purpose of the device** may be made at any time.
  → With regard to the circumstances under which such changes may be considered **«significant»**, see the guidance provided in the MDCG document 2020-3 («Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD»).

EFFECTS / CONSEQUENCES

If all of the conditions and requirements specified above are met with regard to a particular device, the device concerned **may be placed on the market or put into service also after 26 May 2021**, without having to comply with any further requirements (in particular, **without having to obtain a certificate from a *MDR* Notified Body**).

However, such devices may only be **placed on the market until the certificate expires or until 26 May 2024 at longest** (art. 120 par. 3 MDR), and they may only continue to be **made available on the market** or **put into service until 26 May 2025** (art. 120 par. 4 MDR).

In addition, **the Notified Body** that issued the certificate **continues to be responsible for the appropriate surveillance** in respect of all of the applicable requirements relating to the device concerned (art. 120 par. 3, second subparagraph, MDR).