Questions and Answers on Certificates of Free Sale and Article 60 of Regulation (EU) 2017/745

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1. Introduction

This document presents questions and answers about obligations introduced by Article 60 under Regulation (EU) 2017/745 on medical devices (MDR).

Article 60 (1) outlines that member state can issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the CE marking in accordance with this Regulation may be marketed in the Union. It also details the information that should be set out on the certificate of free sale.

Article 60 (1)

For the purpose of export and upon request by ***a manufacturer or an authorised representative****, the Member State* ***in which*** *the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, has its registered place of business on its territory and that the device in question bearing the* ***CE marking in accordance with this Regulation*** *may be marketed in the Union. The certificate of free sale shall set out the Basic UDI-DI of the device as provided to the UDI database under Article 29. Where a notified body has issued a certificate pursuant to Article 56, the certificate of free sale shall set out the unique number identifying the certificate issued by the notified body, as referred to in Section 3 of Chapter II of Annex XII.*

2. Scope

The questions covered by this document aim to guide member states and economic operators carrying out any of the activities mentioned in Article 60 (1) of the Regulation concerning certificate of free sale and outline where the use of national provisions may be required.

3. Questions and Answers

Question 1

Who is responsible for the issuance of a Certificate of Free Sale under Article 60 of the Regulation?

Certificate of Free Sale issued according to Article 60 of the Regulation can be issued by the member state in which a manufacturer or an authorised representative has its registered place of business.

The 'manufacturer' is defined as a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

The 'authorised representative' is defined as any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

Question 2

To whom can a Member State issue a Certificate of Free Sale under Article 60 of the Regulation?

Certificate of Free Sale issued under Article 60 of the Regulation can be issued by the member state to manufacturers or authorised representatives that have their registered place of business in their jurisdiction.

The 'manufacturer' is defined as a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark. Therefore, a *manufacturing site* that is not the manufacturer as defined may not be eligible to request a Certificate of Free Sale.

Question 3

Can Member State issue a Certificate of Free Sale under Article 60 of the Regulations to System and Procedure Pack Producers (SPPP)?

No, Certificate of Free Sale issued under Article 60 of the Regulations can only be issued by the Member State to manufacturers or authorised representatives that have their registered place of business in their jurisdiction.

A SPPP is not a manufacturer of a device and a system or procedure pack is not a device in line with article 1(4) of the MDR and is not typically CE marked.
However, documentation for the purpose of export (e.g.: a statement, a letter, etc.) may be issued to system and procedure pack producers under national provisions.

Question 4

Can a Member State issue a Certificate of Free Sale under Article 60 of the Regulations to System and procedure pack producers (SPPP) that are located outside the Union?

No, Certificate of Free Sale issued under Article 60 of the Regulations can only be issued by the member state to manufacturers or authorised representatives that have their registered place of business in their jurisdiction.
A SPPP is not a manufacturer of a device and a system or procedure pack is not a device in line with article 1(4) of the MDR and is not typically CE marked.
However, documentation for the purpose of export (e.g.: a statement, a letter, etc.) may be issued to system and procedure pack producers under national provisions. However it is not clear which Competent Authority should provide this documentation for system and procedure pack producers (SPPP) that are located outside the Union.[1]

Question 5

Can Member States issue a Certificate of Free Sale under Article 60 of the Regulation to distributors and importers?

No, Certificate of Free Sale issued under article 60 of the Regulation can only be issued by the Member State to manufacturers or authorised representatives that have their registered place of business in their jurisdiction.
It is understood that for some third country distributors and importers may be required to provide supporting documentation. In such instances, it is recommended that a Certificate of free sale be obtained from the member state where the manufacturers or authorised representatives have their registered place of business and that additional documentation for the purpose of export is obtained from the member states where the distributor or importer is located. The additional documentation (e.g.: a statement, a letter, or another type of certificate etc.) would have to be issued under national provisions with no reference to article 60 of the MDR, but it can make a reference that the devices bear the CE mark according to the medical devices legislation.

[1] Regulation (EU) 2017/745 on medical devices (MDR) does not required SPPP located outside of the Union to appoint an Authorised Representative and therefore there it is not clear which CA in the Union should provide a Certificate of Free Sale.

Question 6

What documentation should be provided to a Competent Authority when requesting a Certificate of Free Sale?

The documentation that is required when requesting a Certificate of Free Sale will vary from member state to member state. It is important to check the website or information provided by the Competent Authority in the jurisdiction where manufacturers or authorised representatives have their registered place of business.

The documentation required may include

1. An application form.
2. Copies of the EU Declaration(s) of conformity for the device(s) required to be listed on the certificate of free sale.
3. Copies(s) of the EC certificate(s) for the device(s) required to be listed on the certificate of free sale.
4. Details of the manufacturer and the authorised representative, where applicable, and device(s) registrations.
5. Details of the device(s) basic UDI –DI.
6. A copy of the label and IFU for the devices, where applicable.
7. Copies of ISO certification, where applicable.

The requirement for the documentation outlined above may reduce once Eudamed is fully functional as Economic Operators, devices and certificate information will be available.

Question 7

What details should be included on the Certificate of Free Sale under Art 60 of the Regulation?

The Certificate of Free Sale may include the following details:

1. The name and the address of the manufacturer.
2. The name and address of the authorised representative (where appropriate).
3. The name and the address of the manufacturing site (where appropriate).
4. Details of the Basic UDI- DI.
5. Details of the EU Declaration of Conformity, such as legal framework (MDD/MDR) and date of issue.
6. Details of the EC Certificate, such as Notified Body identification, Certificate Number, legal framework (MDD/MDR), date of issue and validity (where appropriate).
7. A signature or Stamp from the issuing competent authority.

This list is not exhaustive and may vary depending on the issuing competent authority.

Question 8

Should an expiry date be included on a Certificate of Free Sale, and if so how should the expiry date be calculated?

The regulation does not prescribe a specific expiry time for a certificate of free sale. The expiry date assigned will depend on the processes that have been adopted by the national competent authority to whom the request for the certificate of free sale has been made.
Where possible competent authorities should ensure that where an expiry date is assigned that it is aligned with the EU declaration of conformity and the notified body certificates for the devices detailed in the certificate of free sale.
The issuing competent authority assesses the conformity of the devices at the time when the certificate is requested, this ensures that the certificate is valid on the date of issue.

Question 9

Are separate Certificates of Free Sale required for self-declared devices and devices with a notified body certificate or can they be included on one certificate?

It is possible to include on one Certificate of Free Sale both self-declared devices and devices with a notified body certificate. However, this will depend on the processes that have been adopted by the competent authority to whom the request for the certificate of free sale has been made.

Question 10

Can devices relating to different Notified Bodies be included on one certificate?

Yes, this is possible. However, this will depend on the processes that have been adopted by the competent authority to whom the request for the certificate of free sale has been made.

Question 11

Can a Certificate of Free Sale be issued under Article 60 of the Regulation for a list of devices that contains both MDR compliant devices and MDD compliant device?

Certificate of Free Sale, issued in accordance with article 60 of the MDR, can only be issued for MDR Compliant devices.
A Certificate of Free Sale for Devices that were certified under the Directives where they can continue to be placed on the market after the date of application in accordance with

Article 120 (3) must be issued under national provisions.

Question 12

Should Certificate of Free Sale for legacy devices be issued under the MDR or the Directives?

Certificate of Free Sale for legacy devices (devices that were certified under the Directives and continue to be placed on the market under Article 120 (3)) can only be issued under the Directives.

Question 13

Should Certificate of Free Sale for a System and Procedure Pack containing MDR compliant devices and legacy devices be issued under national provision that support the MDR or the Directives?

As mentioned on question 3 Certificate of Free Sale issued under Article 60 of the Regulations may not be issued to a SPP assembler.
Documentation issued by the competent authorities for the purpose of export a SPP containing MDR compliant devices and legacy devices (e.g.: a statement, a letter, etc.) should be issued under national provision that support the MDR.

Question 14

Should documentation issued by the competent authorities for the purpose of export a System and Procedure Pack containing legacy device only be issued under national provision that support the MDR/ or the Directives?

The Certificate of Free Sale for a system and procedure pack containing legacy device only should be issued under national provision that support the MDD.

Question 15

Can a Certificate of Free Sale still be obtained for devices that are compliant with the Directives and for how long will it be possible to obtain such Certificate of Free Sale?

Certificate of Free Sale can continue to be issued, under national provisions for devices that are compliant with the Directives in the following situations:

1. For devices that are compliant with the medical device directives (MD & AIMD) and were placed on the market before the date of application – until they exit the supply chain. (in

accordance with Article 120(4) MDR).

2. For devices that will be up classified under the MDR (in accordance with Article 120(3) MDR).

3. For device that were certified under the directive and continue to be placed on the market under Article 120 (3) of Regulation (EU) 2017/745.

Under Article 120 self- declared and Notified Body certified devices can remain in the supply chain until May 2025. However it must be noted that notify body certificates associated with the Article 120 (3) devices may only be valid until May 2024.
As the Certificates of free sale relating to such devices should be issues under national provisions the issuing competent authority will assess the conformity of the devices at the time when the certificate is requested and determine if a Certificate of Free Sale can be provided. This assessment will depend on the processes that have been adopted by the competent authority.

Question 16

Can Electronic Signatures be used on a Certificate of Free Sale?

Yes, there is nothing precluding member states from using electronic signatures on certificates of free sale. However it must be noted that electronic signatures are not accepted by all third countries.