THE MDR JOURNEY

NEWSLETTER No. 19 – November 2020

«Let's make transparency a standard requirement»

Subject:

Economic Operators and Registrations

Introduction:

In May 2021, Europe's medical device regulation (EU MDR) will go into effect, replacing the existing medical device directive (MDD) that is currently in place.

The EU MDR requires total lifecycle traceability between all stages of medical device development and post-market activities. Demonstrating traceability throughout the product lifecycle, known as closed-loop traceability, is a revolutionary approach to quality management that many industry professionals never thought possible.

To keep track of devices through every lifecycle stage, a device identifier will be assigned and all production series will be marked with a production identifier. These tracking measures satisfy the new mandate for Unique Device Identification (UDI), which is entered into the EUDAMED database.

UDI information must:

- Be placed on the medical device's package or label.
- Follow globally used formats.
- Include the EC representatives' detailed information, including name, address, and symbol.
- Be published electronically to the manufacturer's website (if applicable) and also be available in print.

Under EU MDR, **economic operators** now include manufacturers, authorized representatives, importers, and distributors. These entities will be expected to take on an increased level of responsibilities throughout the medical device supply chain process.

Manufacturer
Indicates the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer adjacent to the symbol. The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. The relevant information can be placed either beside or below the symbol.

Sengewald Klinikprodukte GmbH
Adlerstraße 2, 83101 Rohrdorf,
Germany
2020-11-19

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Authorized representative in the European Community / European Union.
Indicates the authorized representative in the European Community / European Union. For other locations that require identification of the authorized representative, a manufacturer may replace the letters EC with the two or three letter country code for that location.

EC REP Name Address

UK REP Name Address

Importer
Indicates the entity importing the medical device into the locale. This symbol shall be accompanied by the name and address of the importing entity, adjacent to the symbol.

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Adlerstraße 2, 83101 Rohrdorf,
Germany

Sengewald Klinikprodukte GmbH
Adlerstraße 2, 83101 Rohrdorf, Germany

Distributor
Indicates the entity distributing the medical device into the locale. This symbol shall be accompanied by the name and address of the distributing entity adjacent to the symbol.

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Adlerstraße 2, 83101 Rohrdorf,
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Adlerstraße 2, 83101 Rohrdorf,
Germany

Translation
To identify that the original medical device information has undergone a translation which supplements or replaces the original information. This symbol shall be accompanied by the name and address of the entity that is responsible for the translation activity, adjacent to the symbol. This symbol shall only be used when the translation activity was undertaken by someone other than the manufacturer.

Sengewald Klinikprodukte
GmbH Adlerstraße 2, 83101
Rohrdorf, Germany

Sengewald Klinikprodukte GmbH
Adlerstraße 2, 83101 Rohrdorf, Germany

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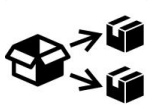
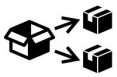


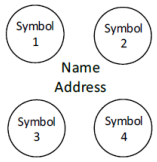
Repackaging

To identify that a modification to the original medical device packaging configuration has occurred. This symbol shall be accompanied by the name and address of the entity that is responsible for the repackaging activity, adjacent to the symbol. Depending on the authority having jurisdiction, additional information (i.e. date of repackaging) can be needed.



Sengewald Klinikprodukte GmbH Adlerstraße 2, 83101 Rohrdorf, Germany

Sengewald Klinikprodukte GmbH
Adlerstraße 2, 83101 Rohrdorf, Germany



If multiple symbols (i.e., Authorized Representative, Importer, Distributor, Translation, or Repackaging) identify the same responsible entity, the name and address need not be duplicated.

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To ensure traceability and safety for devices being marketed in Europe, EU MDR imposes an entirely new set of requirements for importers and distributors (see the previus 2 newsletters).

In addition, new requirements for economic operators include verification of compliance, cooperation in complaint handling and field safety corrective actions, and, of course, cooperating with manufacturers and Competent Authorities in device traceability. The purpose of EUDAMED is to create an accessible repository of device-related information for patients, regulators, notified bodies, and manufacturers to access data for medical devices being marketed in the EU and help improve overall post-market surveillance.

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Let´s have a closer look at registrations deadlines ...

Devices	**MDD Devices - Legacy devices[1]**				**MDR Devices**			
	Assign EUDI	Assign UDIDIs	Register	UDI Carrier on Label	Assign Basic UDI	Assign UDIDIs	Register	**UDI Carrier on Label**
Class I	-	-	-	-	Yes	Yes	26/05/2022 Or immediately in case of Incidents and AE[2]	**26/05/2025**
Class Is	Yes until MDD Certificate is valid	Yes until MDD Certificate is valid	immediately in case of Incidents and AE[2]	-	Yes immediately after MDD Certificate expires	Yes immediately after MDD Certificate expires	26/05/2022 Or immediately in case of Incidents and AE[2]	**26/05/2025**
Class IIa	Yes until MDD Certificate is valid	Yes until MDD Certificate is valid	immediately in case of Incidents and AE[2] 26/11/2022 If certificate expires after this date but before 26/05/2024	-	Yes immediately after MDD Certificate expires	Yes immediately after MDD Certificate expires	26/05/2022 Or immediately in case of Incidents and AE[2]	**26/05/2023**
Class IIb	Yes until MDD Certificate is valid	Yes until MDD Certificate is valid	immediately in case of Incidents and AE [2] 26/11/2022 If certificate expires after this date but before 26/05/2024	-	Yes after MDD Certificate expires	Yes immediately after MDD Certificate expires	26/05/2022 Or immediately in case of Incidents and AE[2]	**26/05/2023**
Class III	Yes until MDD Certificate is valid	Yes until MDD Certificate is valid	immediately in case of Incidents and AE [2] 26/11/2022 If certificate expires after this date but before 26/05/2024	-	Yes immediately after MDD Certificate expires	Yes immediately after MDD Certificate expires	26/05/2022 Or immediately in case of Incidents and AE[2]	**26/05/2021**

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1. Legacy devices – covered by a valid Directive certificate - that will continue to be placed on the market after the MDR date of application should be registered in Eudamed without a Basic UDI-DI and UDI-DI. The registration deadlines for those devices is clearly the one referred to in Article 123(3)(e): 18 months after the date of application (provided that Eudamed is fully functional on time).

2. However, in case of serious incident or field safety corrective action to be reported during the 18 months referred to in point 1, where the legacy devices have not been registered in Eudamed yet, they must be registered at the moment of the serious incident/field safety corrective action reporting.

3. Point 1 will be applicable only to the devices that are not already registered as MDR devices.

NOTE: All the Directive-compliant devices which have been placed on the market ahead of the general application dates and will not continue to be placed on the market afterwards, should be registered in Eudamed (without a Basic UDI-DI and UDI-DI) only if a serious incident report and/or a field safety corrective action report (with the field safety notice) occurs after the application date.

Let´s have a closer look at registrations obligations ...

The European Medical Device Coordinating Group (MDCG) has set a deployment date for an important component of the **Eudamed** database for **registration** of economic operators. According to a recent position paper, MDCG plans a December 1, 2020 **deadline** for rolling out the "actor **registration** module" of **Eudamed**.

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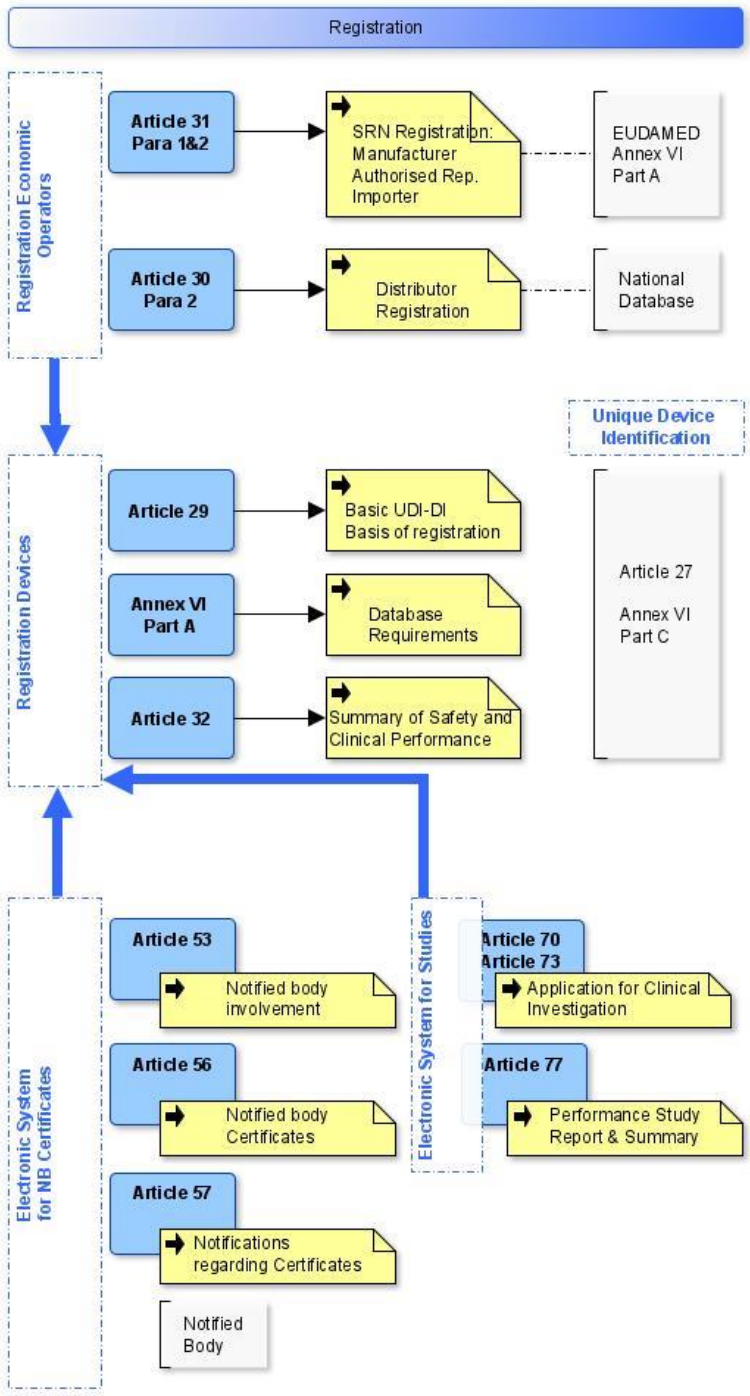

Kick off 1st December 2020

See the table above

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This newsletter is part of our campaign to increase the sensitivity and the awareness of all our business partners, to bring more clarity around the MDR journey and challenges and opportunities around the MDR Art.22 "Systems and Procedure Packs".

We are already today all dependent on an effective cooperation. For the MDR implementation, we require even a closer collaboration in order to ensure we all can deliver safe supply to hospitals and patients in the future.

We are confident we'll be able to continue to supply health care competently on customized surgical procedure sets and small kits.

You want to know more about specific topics? Do you have any questions or comments?

Write us MDR2020@stsmedicalgroup.com

The next MDR Newsletter will be issued in December. We wish everybody pleasant days.

Augusto Orsini
CEO STS Medical Group

Katarzyna Zofia Chrusciel
Corporate Technical Director
Quality Management and Regulatory Affairs