THE MDR JOURNEY

NEWSLETTER No. 23 – March 2021

«Let's make transparency a standard requirement»

Subject:
Article 120 (4) MDR and "sell-off" provision.

In this Newsletter, we want to discuss the EU MDR Article 120(4) transitional provision. This provision pivots on a proper understanding of "placing on the market" under MDD before the date of Application (DoA) of the EU MDR, and then "making available on the market" and "putting into service" after the DoA of the EU MDR. As MDD's and EU MDR's definitions for "placing on the market" are generally interpreted with the same meaning and as "making available" and "putting into service" are in EU MDR Article 120(4) with its corresponding cut-off date, well after the EU MDR application date, it is both necessary and convenient to review the EU MDR's definitions for these three terms

• "making available on the market";

• "placing on the market"; and

• "putting into service."

'**making available on the market'** means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of commercial activity, whether in return for payment or free of charge;

Blue Guide and the Commission's November 16, 2010 guidance definition:

A product is made available on the market and supplied for distribution, consumption, or use in the Union market during a commercial activity, whether in return for payment or free of charge. The concept of making available refers to every single product.

'**placing on the market'** means the first making available of a device, other than an investigational device, on the Union market;

Blue Guide and the Commission's November 16, 2010 guidance definition:

A product is placed on the market when made available for the first time on the Union market. Products made available on the market must comply with the applicable Union harmonization legislation when placing on the market.

'**putting into service'** means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;

We also need to know the Article 2 definition for "distributor" considering the concepts described above, as it also has a bearing on how the facts will be interpreted.

'distributor' means a natural or legal person in the supply chain, besides the Manufacturer or the importer, that makes a device available on the market, up until putting the device into service.

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Suppose an MDD-compliant device is a class I non-sterile, non-measuring, not a reusable surgical instrument, and not up-classified by the EU MDR's classification rules. In that case, it means that the device is a self-declaration device (i.e., there is no involvement of a Notified Body). Such a device is not eligible for participation in the Article 120(2) and/or (3) 2024 transitional buffer and must consequently comply with the EU MDR from May 26, 2021. The MDD Declaration of Conformity (DoC) for such a device is legislatively invalid and terminated from May 26, 2021.
But suppose an MDD-compliant device is, for example, class I sterile or measuring and will remain so under the EU MDR's classification rules. In that case, the product is eligible for participation in the Article 120(2) and/or (3) 2024 transitional buffer. In that case, the MDD DoC can remain as it is until replaced and/or supplemented by an EU MDR certificate and DoC.

But what if the class I nonsterile medical device is legally marketed under the MDD and delivered to the distributor before May 26, 2021?

It is needed to apply the so-called "sell-off provision" in EU MDR transitional Article 120(4) regarding devices legally marketed under the MDD (i.e., commercialized before May 26, 2021).

Doc and/or MDD certificates might expire while the devices are still available in the Union marketplace (like in a European distributor's inventory).

What is the so-called "sell-off" provision (Art. 120 para 4 MDR) about?

"Devices lawfully placed on the market according to Directives 93/42/EEC (MDD) before May 26, 2021, and devices placed on the market from May 26, 2021, under a certificate as referred to in paragraph 2 of this Article, may continue to be made available on the market or put into service until May 27, 2025."

It is intended to limit the time during which MDD compliant devices that have already been placed on the market (either before the DoA or under Art. 120 paragraph 3 DoA) might be available, e.g., by a distributor.

After May 27, 2025, these devices may not be made available/put into service (= deadline). If such devices are still within the supply chain by this date - i.e., have not reached the final user as ready for use (e.g., the hospital) - they are not "marketable" anymore.

Thus, this provision is primarily dealing with the "making available" of MDD compliant devices once they have been placed on the market, e.g. within the supply chain. It does not apply to the "placing on the market" of these devices by the Manufacturer.

Please also note that this provision is not intended to apply to second-hand sales. This means, once a device has been made available to the final user (e.g., the hospital) as being ready for use, the further making available of this device is not subject to/covered by the MDR.

The "sell-off" provision is for devices placed on the market (e.g., delivered to a European distributor) before the May 26, 2021 expiry of a device's MDD DoC and/or MDD EC Certificate. **The "sell-off" provision establishes the period after that, specifically, May 26, 2025, within which the device can continue to be made available on the market.**

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If we don't leverage the EU MDR's entry into force, thereby failing to apply EU MDR Article 120(4) for MDD-devices sold before the application date of the EU MDR, then from May 26, 2021, we would generally be forced to recall all such products from the EU marketplace even though it was legally marketed.

We must remember that "placing on the market" requires an offer or an agreement (written or verbal) between two or more legal or natural persons to transfer ownership, possession, or any other property right concerning the product. It is that very type of transfer that is the object of Article 120(4). By contrast, Article 120(4) is not intended for the mere transfer of devices into a manufacturer's warehouse, as that doesn't generally meet the definition of "placing on the market."

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 practical cooperation. For the MDR implementation, we require even closer collaboration to ensure we all can deliver safe supply to hospitals and patients in the future.

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

Do 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 April. We wish everybody pleasant days.

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