AliveCor®

MDR transition for EU customers

Dear Client,

The European Medical Device Regulation (EU-MDR) has replaced the European Medical Device Directives (MDD) for Medical Devices.

In this communication we want to outline the commercial distribution of AliveCor's KardiaMobile Medical Sensors and Smartphone App in the European Economic Area (EEA) before and after expiration of its CE-Mark Certificate in January 2023 in accordance with EU-MDR Article 120 Transitional Provision.

Important to know is that the European regulatory framework for medical devices depends on the validity of a product family specific CE-Mark certificate. This Certificate is issued by a so-called Notified Body e.g., TÜV SÜD for the legal manufacturer AliveCor Inc. The Declaration of Conformity (DoC) is issued by AliveCor Inc. in California ensuring all applicable regulatory requirements are met at the time of signature date.

The EU-MDR Article 120 Transitional Provision pivots on a proper understanding of regulatory concepts such as "placing on the market" after the EU MDR became effective on **26 May 2021** and then "making available on the market" and "putting into service" after this date and after AliveCor's current MDD CE-Mark certificate expires on **14 January 2023**.

What does "placing on the EU market" mean?

A product is placed on the market when it is **made available for the first time on the Union market**.
Each **individual product can only be placed once** on the Union market.

Products made available on the market must comply with all applicable Union harmonization legislation at the time of placing them on the market.

What does "making available on the EU market" mean?

Any supply of a commercial medical device, its distribution, its consumption or use in the Union market in the course of commercial activity, whether in return for payment or free of charge.

We must also 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 does not generally meet the definition of "placing on the market."

What does "putting into service" mean?

It is the stage at which a commercial medical device has been made available to the end-user as being ready for use in the Union market for the first time for its intended purpose.

What are "Legacy Devices"?
Legacy Devices are defined as Medical Devices that are covered by a valid MDD CE-Mark Certificate and continue to be placed on the market after the MDR became effective on **May 26 2021**.

AliveCor's Ambulatory Electrocardiographs (KardiaMobile / KardiaMobile 6L), Software Apps and Algorithms used in Screening, Diagnosis and Management of Heart Rhythm Disorders (Kardia App / KardiaStation App / Kardia SDK) are considered Legacy Devices.

What is the so-called "sell-off" provision (Art. 120 (4) MDR) about?
It is intended to limit the time during which legacy devices that have already been placed on the market (either prior or under Art. 120 paragraph 3) might be available by a distributor.

After May 26, 2025, these devices may not be made available/put into service. 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.

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

What does the MDR Transition Provision mean for AliveCor's Legacy Devices?
The MDD CE-Mark Certificate for AliveCor KardiaMobile Software and Hardware legacy devices issued by TÜV SÜD Product Service will expire on **14 January 2023**. After that date no AliveCor legacy device can be imported or placed on the European Market for commercial distribution.

Please note: *The MDD CE-Mark certificate will expire while the imported AliveCor Legacy Devices are still available for distribution in the Union marketplace (e.g., European distributor's inventory warehouse).*

How does AliveCor ensure distribution of Legacy Devices continues after 14 January 2023?
AliveCor follows a contingency plan and will place/import enough legacy devices into the European market for commercial distribution until a new MDR CE-Mark Certificate is available.

Please note: *Once a legacy device is imported i.e., placed on the European market it can be stored in a warehouse for distribution even after the MDD CE-Mark Certificate expires until latest* ***26 May 2025****.*

How does this work for AliveCor's Legacy Smartphone Apps?
The cited medical device regulations define import and distribution requirements for physical medical devices. Medical Software apps are not physically placed on the market for distribution. Therefore, the cited regulations fell short on regulating software as a stand-alone medical device. However, legacy medical software apps are so called Software as a Medical Device (SaMD). Software Apps are considered placed on the European market when offered for the first time to a European end-user by means of online distribution.

Please note: *Legacy medical software apps must conform to the same regulatory requirements at the time first placed on the EU market for distribution/download e.g., allowing European end-users to install the medical device software for use on Smartphones.*

Can AliveCor change its legacy device characteristics during the Transition Period?
Yes. However, only minor device modifications are permitted, excluding major design changes and intended use or medical purpose.

Any proposed change to a legacy medical device during the EU-MDR transition period requires a rigorous regulatory assessment to determine the nature and impact of proposed modifications to safety, performance and medical purpose avoiding regulatory uncertainties.

What about Software updates and modifications to AliveCor's KardiaMobile Legacy App? Can AliveCor still maintain functionality, performance, and safety for the legacy App during the transition period?

Yes. AliveCor is legally mandated to maintain safety, performance, and functionality of the KardiaMobile Smartphone App's for its entire life cycle.

According to the Blue Guide on the implementation of EU product rules 2022[2], medical device software updates or repairs are considered maintenance operations provided that they do not modify the Legacy Smartphone App already placed on the market in such a way that regulatory compliance at the time first placed on the European market is compromised.

Please note: *Maintenance and update revisions of the legacy app are subject to AliveCor's QM System for Software development.*

Further guidance is provided in MDCG 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".

Is there an overview summarizing what is important for AliveCor's Legacy Devices in the EU Market during the MDR Transition Period?

Please see below the transition timeline and cut-off dates for AliveCor's Legacy Devices.

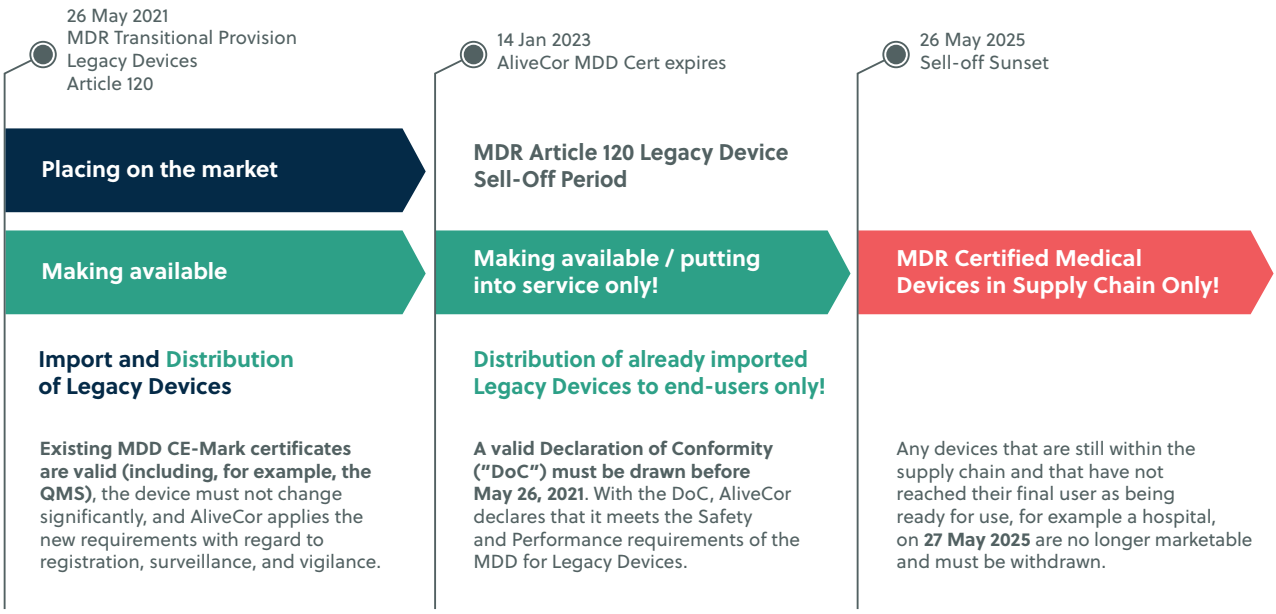

Figure 1. MDR Transition Timeline for AliveCor Legacy Devices

[2] Blue Guide on the implementation of EU product rules 2022

This Newsletter is part of our communication to increase the awareness of all our business partners, to bring more clarity around the MDR journey as well as challenges and opportunities for AliveCor KardiaMobile sensors and medical Smartphone apps.

We are already benefitting from our mutual cooperation. For the MDR implementation, we are looking forward to even closer collaboration ensuring safe supply to our patients and physicians in the future.

Do you want to know more about specific topics? Do you have any questions or comments? Please contact your local AliveCor representative.