UPDATE

THE IN VITRO DIAGNOSTICS REGULATION (IVDR)

MetaSystems Customer Information - August 2022

Transition periods for the IVDR have been partially extended.

The effective date of the In Vitro Diagnostics Regulation (**IVDR**; Regulation (EU) 2017|746) remains May 26, 2022. However, a progressive roll-out of the new IVDR was decided for existing products. This means that products, for which compliance has been declared before May 26, 2022, and which do not fall into Class A under the IVDR, the deadlines have been prolonged. The EU Commission justified the additional prolongation with the impact of the Covid-19 pandemic that has tied up many resources and thus made it difficult to fully meet the requirements of the IVDR until May 26, 2022.

We have reacted to this change and are consecutively preparing the CE certification process for our products in accordance with the IVDR. The development of the latest version of our renowned scanning and imaging software Metafer was completed and has been released as Metafer 4.3.

In terms of the current version 6.3 of our karyotyping software Ikaros, we aimed for a CE-marking of the software as a standalone product (Software as a Medical Device; SaMD) under the In Vitro Diagnostics Directive (**IVDD**; Directive 98/79/EC). The next, completely revised, and improved version of Ikaros, Ikaros 7, is already in development and we hope to conduct the conformity assessment under the IVDR in the first quarter of 2023.

What does the IVDR change for our customers?

On May 26, 2022, In Vitro Diagnostics Regulation (**IVDR**; Regulation (EU) 2017|746) became mandatory and has replaced the In Vitro Diagnostics Directive (**IVDD**; Directive 98/79/EC). As of this effective date, the requirements of the new regulation will apply. Important changes in the new regulation include the extension of the scope, a new classification system, and the introduction of a unique device identification number.

For this, MetaSystems prepared CE certification according to IVDR for the new software version Metafer 4.3. The innovations had some impact on our product structure and update capabilities. This document is intended to help you assess the situation and educate you on the measures to be taken, so that you can benefit from future innovations, for example in the field of artificial intelligence.

What did change in the product structure?

With the introduction of the IVDR, we changed our product structure, firstly to make it more transparent and secondly to meet the requirements of the new regulations. At the same time, however, we have endeavored to enable the transition to the new product structure for older systems as well.

New software modules facilitate the creation of networks with distributed roles and with complex workflows.

From May 26, 2022, we offer our products in the form of software licenses or license bundles; we register only these, and not the entire systems, as in vitro diagnostic medical devices (IVD). The corresponding CE label does therefore no longer apply to the hardware supplied with the software (e.g., computers, cameras, etc.). Nevertheless, we are still able to offer the hardware tested and recommended by us together with the software, to assemble it into a complete system, and to deliver it in this form.

To simplify the product landscape, we divided our software products according to application areas (e.g., Automatic Search, Image Acquisition, Karyotyping, Reporting). Product names have therefore changed. For an overview of software modules, please visit the Metafer or Ikaros website.

Isis functionality is part of Ikaros 6.3.

In the process of transition to IVDR, the product name Isis and the functions that were previously offered as Isis have been merged into the new overall package of the Ikaros 6.3 software. When updating an existing system, we will of course adapt your licenses so that the range of functions does not change to your disadvantage.

The modules for CGH and Telomere Length Measurements are no longer offered in Ikaros 6.3.

As part of the new structuring of Ikaros, some little-used functions are no longer available as of version 6.3. MetaSystems has decided to discontinue the functions for so-called *Comparative Genomic Hybridization* (CGH) and for telomere length measurements. The removal of little-used software functions allows us to focus on the further development of other functions.

What does the changeover to the IVDR mean for me and my MetaSystems products?

For manufacturers of in vitro diagnostic medical devices, including MetaSystems, compliance with the new requirements of the IVDR must be demonstrated until the prolonged transition periods end. The IVDR determines in many details how medical devices are manufactured, tested, and used. While MetaSystems has long worked based on the In Vitro Diagnostics Directive (IVDD), the introduction of the IVDR results in additional aspects that must be considered. MetaSystems has set itself the goal of making the transition from the old to the new set of regulations as simple and trouble-free as possible for all our customers.

System integration remains possible.

The medical product for which MetaSystems acts as manufacturer is the respective software license. The appropriate hardware (PCs, microscopes, etc.) continues to be available in the form of supplementary packages, and we also offer the integration of software and hardware into systems and laboratory-wide solutions as usual.

The new software version Metafer 4.3 is certified according to IVDR.

MetaSystems sought CE certification for the new software version Metafer 4.3 under the IVDR. However, we do not submit previous software versions for recertification. **Basically, you can continue to use your existing devices unchanged.** However, from May 26, 2022, we are only allowed to sell Metafer as Software as a Medical Device (SaMD) under the IVDR. This means that older systems will also have to be adapted to the new guidelines if, for example, an extension system is to be integrated into an existing system environment, or if the software is updated. Therefore, we are not able to continue developing and maintaining older software versions from May 2022.

In summary, therefore, ...

- ... the previous versions of Metafer do not receive any further upgrades or updates,
- ... the previous versions of Metafer may no longer be sold within the EU after May 26, 2022,
- ... for upgrades/updates or extensions of existing Metafer installations after May 26, 2022, a renewal of older software versions to the version Metafer 4.3 or higher certified according to IVDR is mandatory,
- ... upgrades/updates or new purchases to existing Metafer installations after May 26, 2022, will in some cases require renewal of hardware of existing installations to ensure compatibility with the IVDR-certified version Metafer 4.3 or higher.

The software version Ikaros 6.3 as SaMD was certified under the IVDD

MetaSystems expects to distribute present CE-certified Ikaros versions through 2023. In parallel, we are developing a new, completely revised version Ikaros 7.0, which we plan to register as an IVDR product. **Basically, you can continue to use your existing devices unchanged.** Until the end of the prolonged transition period, we will be able to sell extension software licenses and updates for existing Ikaros installations as before.

In summary, therefore, ...

- ... the previous versions of Ikaros will not receive any further upgrades or updates,
- ... the previous versions of Ikaros may be sold within the EU until the end of the prolonged transition period.

What are the costs for updating my MetaSystems products?

The costs of updating older software versions depends on the software licenses used, the age of the devices, and the condition/age of the hardware.

Software updates

Our software licenses are always updateable, regardless of their age. MetaSystems calculates the development costs for the years after installation or after the last update and charges a corresponding annual update premium. To facilitate the update of very old software versions, a maximum of 7 years will be charged.

In addition, we offer favorable conditions within the scope of software update contracts. For example, when concluding a five-year contract, the update effort can be reduced to the cost of one year, and this is independent of the age of the software.

Hardware replacement

In principle, we recommend that you continuously update the hardware of a MetaSystems installation. Unfortunately, due to changes in security standards, PC components, in particular, very quickly become obsolete. We recommend replacing the PC hardware every three years, or after 5 years at the latest.

Currently, we produce and test our software exclusively in an environment that allows the operation of Windows 10 64bit. All other, older operating systems are no longer supported by either the manufacturer or MetaSystems and are also to be classified as questionable from a security point of view. As a result, all components must also be able to run under this operating system, which may make the continued operation of older hardware components impossible. In individual cases, we will be happy to advise you on this and offer you ways to replace the old components as cost-effectively as possible. Often, the renewal of the hardware is also associated with a significant improvement in performance.

The information refers to the following software versions: Ikaros 6.3 | Metafer 4.3.
MetaSystems software and system products are classified as in vitro diagnostic medical devices (IVD) in the European Union in accordance with the Regulation (EU) 2017/746 or Directive 98/79/EC, respectively, and carry the CE label unless otherwise indicated. Use all MetaSystems products only within the scope of their intended purpose.
MetaSystems products are used in many countries worldwide. Depending on the regulations of the respective country or region, some products may not be used for clinical diagnostics.
Some hardware components supplied by other manufacturers are not included in MetaSystems IVD products and are therefore not IVD medical devices.

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