

# THE IN VITRO DIAGNOSTICS REGULATION (IVDR)

*MetaSystems customer information - September 2021*

## **What will the IVDR change for our customers?**

On May 26, 2022, the transition period from the In Vitro Diagnostics Directive (IVDD; Directive 98/79/EC) to the In Vitro Diagnostics Regulation (**IVDR**; Regulation (EU) 2017 | 746) will end. As of this effective date, the requirements of the new regulation will apply in full. 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 is preparing CE certification according to IVDR for the new software versions Ikaros 6.3 and Metafer 4.3. The innovations will have 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 make your MetaSystems device(s) IVDR compliant as smoothly as possible, so that you can benefit from future innovations, for example in the field of artificial intelligence.

## **What changes in the product structure are planned for May 2022?**

With the introduction of the IVDR, we will be changing 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.*

In the future, we will offer our products in the form of software licenses or license bundles; we will register only these, and not the entire systems, as in vitro diagnostic devices (IVD). The corresponding CE label will therefore no longer apply to the hardware supplied with the software (e.g., computers, cameras, etc.). Nevertheless, we will still be able to offer to deliver 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 will divide our software products according to application areas (e.g., Automatic Search, Image Acquisition, Karyotyping, Reporting). Product names will therefore change; we will communicate the planned changes later.

# IVDR

---



*Isis functionality becomes 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 will be 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 will no longer be 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 medical devices, including MetaSystems, compliance with the new requirements of the IVDR must be demonstrated as of May 26, 2022. 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 will be the respective software license. The appropriate hardware (PCs, microscopes, etc.) will continue to be available in the form of supplementary packages, and we will also offer the integration of software and hardware into systems and laboratory-wide solutions as usual.

*The new software versions Ikaros 6.3 and Metafer 4.3 are certified according to IVDR.*

MetaSystems is seeking CE certification for the latest software versions Ikaros 6.3 and Metafer 4.3. However, we will not submit previous software versions for recertification. **Basically, you can continue to use your existing devices unchanged.** However, by May 26, 2022, at the latest, we will only be allowed to sell products that are IVDR certified. 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

# IVDR

---



system environment, or if the software is updated. Therefore, we will not be able to continue developing and maintaining older software versions from May 2022.

In summary, therefore, ...

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

*Can I make my devices IVDR compliant?*

Yes. MetaSystems generally keeps an update path open for all licenses in use. This means that all software versions, regardless of age, can be made IVDR compliant. This includes updating the software to the IVDR version and, if necessary, replacing older hardware that is no longer supported.

### **What are the costs for updating my MetaSystems products?**

The cost 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.

# IVDR

---



### *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 that the PC hardware be replaced 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.

# IVDR

---

