# «The changes are significant and should not be underestimated»

**Angelina Hakim**
**CEO & Founder**
**QUNIQUE GmbH**

**Dr. Andreas Stange**
**Vice President**
**MHS Global IVD TÜV SÜD**

The In-Vitro Diagnostics Regulation (IVDR) came in to force on the 26th of May 2017. Unlike the Medical Device Regulation (MDR), the IVDR has a transition period of 5 years. This means that the IVD manufacturers have to fulfil the requirements of the IVDR before the 26th of May 2022. This sounds like a long transition period, especially when compared to the 3 years of transition granted to the medical device manufacturers. However, considering the magnitude of changes and their impact on manufacturers and regulators, the 5 years transition period might even be too short.

I had the opportunity to meet with Dr. Andreas Stange, Vice President of In-Vitro Diagnostics at TÜV SÜD and had the following discussion:

## What can you tell us about the preparations in the IVD industry?

**Dr. Andreas Stange:**

*The IVD industry in Europe has certainly understood that the legislation is changing, and especially big players have started intensive preparation work. Surveys indicate however, that small and medium players are not yet fully grasping the implications.*

## Are IVD manufacturers a bit more relaxed due to the longer transition period?

**Dr. Andreas Stange:**

*It is true that the 3 years transition period for the MDR is shorter, and therefore, the 5 years transition time for the IVDR might appear relatively long. However, the changes, especially concerning classification and the involvement of Notified Bodies in the conformity assessment are significant and should not be underestimated.*

## In the implementation of the IVDR, which topics do you think are the most time consuming for manufacturers?

**Dr. Andreas Stange:**

*The preparation of the technical documentation, especially for companies with a broader product portfolio will demand resources. Documentation requirements for clinical evidence will challenge manufacturers who have to date only placed general IVD devices (so called self-declared devices) on the European market.*

## Do you expect bottle necks due to reduced number of Notified Bodies and their capacities?

***Dr. Andreas Stange:***

*The designation process is underway and there are no exact numbers available, but we understand that the number of Notified Bodies will be reduced by 50% or more. With a much higher involvement in the conformity assessment processes the remaining Notified Bodies will become very busy and their capacity might not be readily available.*

## What can manufacturers do to avoid this bottle neck situation?

**Dr. Andreas Stange:**

*Manufacturers should get in touch with their Notified Body, inquire about the status of their designation and discuss their plans as early as possible. With that, both partners can avoid surprises and address potential resource bottle necks early on.*

## Can you share with us first steps that each manufacturer needs to consider in their preparation for IVDR?

**Dr. Andreas Stange:**

*Manufacturers need to understand that the IVDR will affect not only RA and QA teams, but the whole organization. They should look at their product portfolio and make an impact assessment of the classification rules. Finally, early discussions with Notified Bodies as well as the partnering economic operators will enable better planning and prevent last minute surprises.*

I would like to thank Andreas for his availability and willingness to share with us his valuable insights.

We are looking to welcome Dr. Andreas Stange in Zürich on the 12th of February 2019 as key speaker at our QUNIQUE IVDR Event "Notified Body meets Experts from the Industry".