**TEXT – med mindre ändringar o ett tillägg från Anna-Karin och Språkkorr av Krish**

**Publication of Regulation (EU) 2022/112 - A Risk based roll-out plan for certain in vitro diagnostic medical devices and in-house devices**

On 28 January 2022 the Regulation (EU) 2022/112 (CELEX number [32022R0112](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R0112" \t "_blank)), amending new and updated transitional provisions to the IVD Regulation (EU) 2017/746, was published in the EU's Official Journal after being signed on 25 January 2022 by the Presidents of the European Parliament and Council.

That means that this amending Regulation is now binding in its entirety and directly applicable in all Member States.

However, the amending Regulation does not change any requirements of the original IVD Regulation. It only changes requirement related dates of application identified in IVD Regulation (EU) 2017/746 articles 110, 112 and 113 for certain IVD medical devices including in-house devices.

The purpose of Regulation (EU) 2022/112 is to prevent disruption of supply of essential healthcare products in the context of the COVID-19 pandemic. All manufacturers need to control how the amending regulation affects transition times for each device.

Första textutkastet från Micke:

Publication of Regulation (EU) 2022/112 - A Risk based roll-out plan for certain in vitro diagnostic medical devices and in-house devices

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