



ISO 80369-7 Compliance Update – April 2021

Dear Valued Customer:

As a medical component supplier, we make it our priority to stay abreast of regulatory changes and safety standards in the industry, and provide you with solutions to achieve compliance, minimize patient risk and be innovative when designing devices.

With the impending publication of the newly revised ISO 80369-7—**estimated to occur by August 2021**—we understand you may have questions and concerns regarding the publication date, and the measures Qosina is taking to ensure our components are in compliance.

Reinstatement of ISO 594-1 and 594-2

As you are aware, ISO 80369-7 replaced ISO 594-1 and ISO 594-2, the previous governing standards for conical luers for use with hypodermic syringes and needles. In late 2019, the FDA removed the withdrawal date of ISO 594-1/2 and announced the continued acceptance of ISO 594-1/2 and ISO 80369-7 as consensus standards. Once the updated ISO 80369-7 is published, it will be recognized as the superseding standard to both the current ISO 80369-7 and ISO 594-1/2. From there, a transition period will occur and will be **no less than one year** from the date the new standard is published.

What does this mean for medical components?

Since the development of ISO 80369-7 in 2016, medical device component manufacturers began working diligently to ensure their products were compliant well in advance of the originally assigned October 2021 deadline. Given that the FDA has pushed back this “go live” date, most manufacturers have ceased testing for now and will resume once the update has been finalized. If you’d like to find out which of our components are compliant, please visit our dedicated ISO 80369-7 product section on our website at <https://www.qosina.com/iso-80369-7>. All of our components that currently meet the guidelines as stated in ISO 594-1/2 or ISO 80369-7 remain in compliance.

We continue to closely monitor the new ISO 80369-7 publication date and will release updates as we receive them. If you would like to have them delivered directly to your inbox, please click [here](#).

Once the update is published, please feel free to reach out to our sales team at sales@qosina.com if you require assistance during the research and testing phases of your design process.

Sincerely,

Ken Wolcott
Vice President of Product Development