HOW COVID-19 WILL IMPACT MEDICAL DEVICE TRENDS IN 2021

And the expanding role of translation

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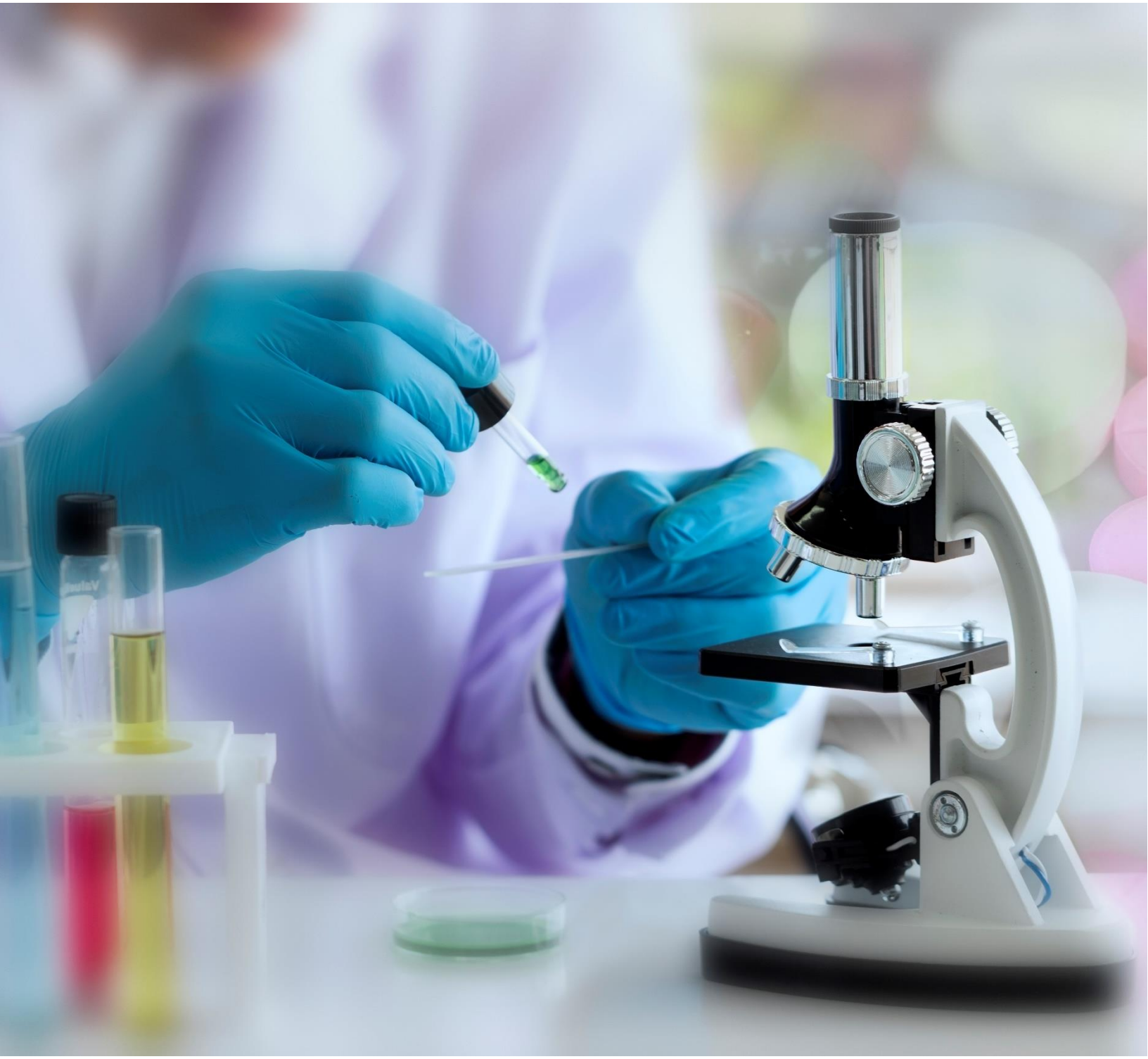
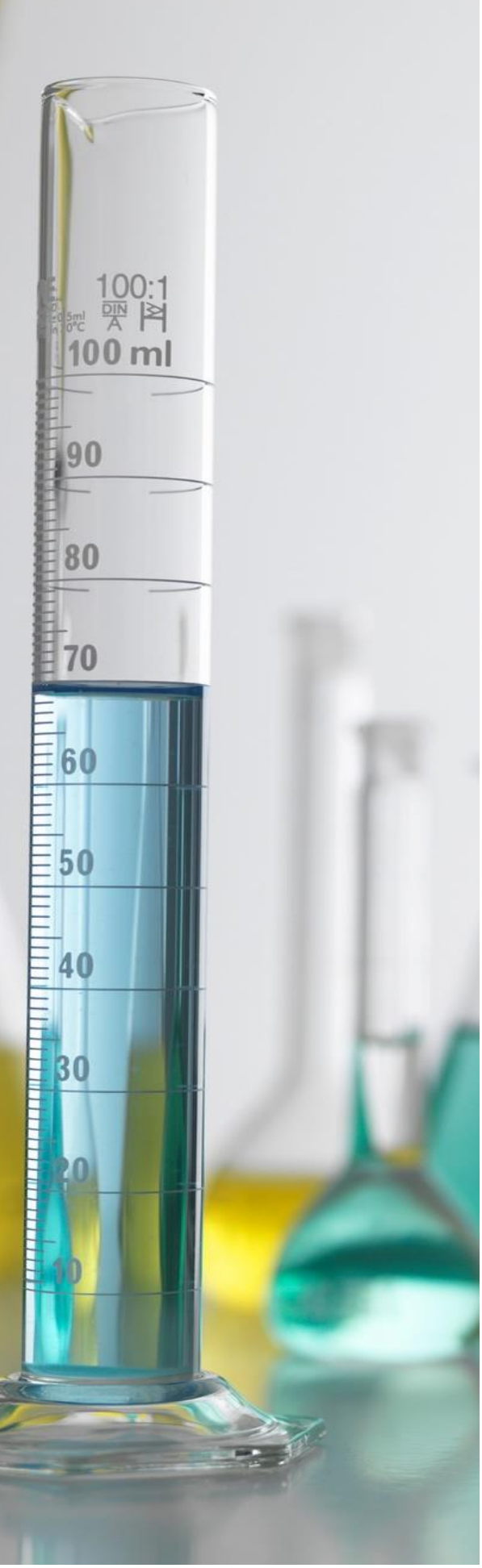


ABSTRACT

The COVID-19 pandemic has created a year-long crisis among healthcare providers and their suppliers. To deal with this crisis, the EU postponed the application date of its MDR regulation. This statute requires medical device makers to produce more information, all translated into the EU's 24 official languages. Learning how to prepare material for the upcoming May 2021 deadline is essential for all medical device manufacturers. This paper will outline the road to full compliance with the new EU MDR regulation.



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INTRODUCTION: HOW COVID-19 IMPACTED THE MDR ROLLOUT

The COVID-19 global pandemic has brought massive change throughout the world. Nowhere has this disease had a more profound impact than on the medical device industry – and on those who translate the devices' brochures, operating manuals, and other critical documents.

Due to this novel coronavirus, demand for Class I and II devices, such as medical-grade masks, skyrocketed. For that reason, the European Commission (EC) postponed the date that its new Medical Devices Regulation (MDR) would go into effect by a full year, pushing the date from May 26, 2020 to May 26, 2021 (1).

With the EU's need for "vitally important medical devices" guaranteed to increase during 2020, the Commission postponed the application date to allow new devices on the market to provide faster aid in the fight against the virus. Medical industries, as the EC's Margaritis Schinas put it, could then put "all their energy into what we need them to be doing: helping fight the pandemic."

Avoiding the disruption that a new slew of regulations would cause unleashed medical device manufacturers' innovation, alleviating delays or shortages. It was a win-win situation all around, providing EU citizens with the latest in medical equipment during the pandemic's height.

With only a few months left until the new regulation's reporting requirement begins, medical device makers and the translation companies they partner with must face several challenges in meeting the demands of the ongoing pandemic and preparing for the new regulation to go into effect (2). This paper will address those challenges.