



April 5, 2021

Dear Surgeon Partner,

As a valued partner, we want to make sure you are aware about the latest information regarding our products.

NuVasive Specialized Orthopedics (NSO) received notification from DQS Medizinprodukte GmbH (DQS), its notified body, that the CE certification for all variations of the MAGEC and Precice device systems has been temporarily suspended. All sales of these products in countries requiring a CE Mark are on hold.

NSO is committed to upholding a high level of quality for our products, and we believe in the safety and efficacy of the MAGEC and Precice device systems. Patients with implanted devices may continue treatment in consultation with their healthcare provider.

As previously communicated in a [Field Safety Notice](#) for the MAGEC device, DQS and NSO have been working together in review of the MAGEC system. Over the course of the review and through parallel efforts, evidence gaps for the MAGEC and Precice device systems were identified and we have been actively working to satisfy these requirements. DQS moved forward with a notification to temporarily suspend CE certification for the MAGEC and Precice device systems while we resolve these gaps. In addition, NSO has voluntarily initiated a ship hold on the MAGEC and Precice device systems in countries not requiring a CE Mark as the Company engages with local regulatory bodies on these products.

We are confident in our action plan in place and we will continue to work diligently with DQS to provide the requested information, satisfy regulatory requirements, and reinstate our CE certification to make these products available for patients as soon as possible.

In addition to sharing this with you directly, this letter is also posted on our website for [MAGEC](#) and [Precice](#). Please reach out to your NSO or NuVasive representative with any questions—our team is here to support you and your patients.

Sincerely,

Kyle T. Malone

Vice President, Clinical, Medical, & Regulatory
Affairs
NuVasive, Inc.

Matthew Collins

Vice President, Global Quality Assurance
NuVasive, Inc.