



Originally posted April 5, 2021  
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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. As stated in prior Field Safety Notices (FSN) for [MAGEC](#) and [Precice](#), prophylactic removal of functioning devices is not recommended, and any treatment decisions should be made in consultation with the patient and/or family.

As previously communicated in a [European Union \(EU\) FSN](#), 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, as communicated in EU FSNs for [MAGEC](#) and [Precice](#). 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 voluntarily issued 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. These products are unavailable while the voluntary ship hold is in place and your NSO or NuVasive representative will update you on product availability.

We are confident in our action plan in place and we will continue to work diligently with DQS and local regulatory bodies to provide the requested information and/or satisfy regulatory requirements 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](#) notices. 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.