

Sent by email

To Whom it May Concern

The PRECICE system, inclusive of PRECICE IMLL, PRECICE Freedom, PRECICE Unyte, PRECICE Opty-line, PRECICE Stryde, PRECICE Bone Transport, and PRECICE Plate system (class IIb) manufactured by NSO Specialized Orthopedics, Inc. (NSO)

On 30 March 2021, NSO received notification from DQS Medizinprodukte GmbH (**DQS**) - the European Notified Body for the PRECICE System (inclusive of all devices above) - that as of 30 March 2021, DQS is restricting certificate Ref. No. 451319 MR2 for the PRECICE Devices through a suspension of the CE mark, meaning that NSO is not currently able to market the PRECICE Devices with the CE mark.

Whilst we are aware that DQS will be informing you separately, NSO is committed to proactively engaging with competent authorities and regulators in relation to this development and we are therefore bringing DQS's notification to your attention as soon as possible.

Although NSO is confident that the PRECICE Devices meet all required standards, NSO is carefully considering the suspension decision of the CE mark received from DQS. Together with that CE suspension notification, NSO is working with DQS on an action plan aimed at resolving its concerns regarding the PRECICE Devices, and NSO is confident it is in a position to provide information sufficient to satisfy the DQS action plan and enable DQS to lift the restriction on the certificate.

As an immediate measure, NSO has taken steps to ensure that it provides no PRECICE Devices to markets that require a CE mark at this time (though notes that a small number of PRECICE Devices, CE marked prior to being notified of the suspension, may already be in the supply chain in the hands of third-party distributors). We are also notifying users of the PRECICE devices, informing them about the suspension of the CE mark and the current inability of NSO to fill any orders for the PRECICE devices.

Please do not hesitate to contact me with any questions related to the DQS's suspension of the certificate for the PRECICE Devices.

Yours sincerely,

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Leader – Clinical, Medical, & Regulatory Affairs
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