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Dear Valued Precision Medical Customer:

On Wednesday June 12th, Precision Medical's notifying body, Lloyd's Register Quality Assurance (LRQA) announced that they will not apply to be a notified body (NB) for the new medical device and in vitro diagnostic regulations (MDR/IVDR), nor will they push ahead with plans to mitigate the potential fallout from Brexit by establishing a presence in the Netherlands. LRQA has advised clients to find a new notified body and has given all clients a ninety-day notice to prepare for the transition.

LRQA's decision to withdraw from its NB services is likely a consequence of the complexity required to become accredited for MDR/IVDR. It comes as a surprise to our team, and to many other medical device manufacturers who will now be without a notified body. This action by LRQA is a business decision and does not reflect the quality of Precision Medical products, which have provided safe and effective patient care throughout the world for over 30 years.

As many of you know, we have been unable to ship products requiring CE certification for quite some time. We have been in constant contact with LRQA and they have assured us that we are on a priority list for review with a tentative restoration date of late July 2019.

Precision Medical will be able to ship CE certified product from the date our CE certification is restored through the end of LRQA's ninety-day notice period, or September 12, 2019. After September 12, 2019, Precision Medical's CE will no longer be valid due to Lloyd's decision to withdraw from its notified body services. We are applying to the only two accredited notified bodies currently able to meet the standards of the MDR/IVDR. However, due to the sudden and surprising nature of this withdrawal by LRQA, it is to be expected that the list of applicants will be long, resulting in a lengthy transition period.

Regardless of the status of our CE certification, Precision Medical will continue to support all products in the field. Thank you for your many years of business partnership, we look forward to meeting this new challenge and to providing you many more years of customer service.

Regards,
The Management Team of Precision Medical