

Reference: ISO13485:2016 Certification

Dear valued customer,

This letter is to address the delay in receiving our updated ISO13485 certificates; our certificates expired on the 6th February 2018.

Sterimedix has completed the transitional audit to ISO13485:2016 with only 4 minors raised. However, our notified body, SGS, has been having difficulty in providing us with the updated certificates. While we are waiting confirmation of dates, SGS will be issuing a letter which will cover the delay.

I can assure you that this will not affect how Sterimedix operates its quality management system and we will continue to maintain the highest standards possible.

Sterimedix still possess a valid CE certificate so we will resume supply of product where possible.

As soon as we receive the letter from SGS we will forward this to you to keep on file. The moment we receive the ISO certificates we will forward these to you immediately.

I hope that this letter addresses any concerns that you may have, but if you have any further queries please do not hesitate to contact me.

Yours sincerely



Andrew Ellis
Quality and Regulatory Manager