

bluepoint medical GmbH & Co. KG
An der Trave 15
23923 Selmsdorf

Hamburg, 2019.02.26

Transition to EN ISO 13485:2016

With EN ISO 13485:2016 becoming the only valid revision of the standard on 1 April 2019, a large number of certifications are currently undergoing evaluation of changed requirements and pending issue of certificates against EN ISO 13485:2016. The large number of reviews may cause delays in completion of these activities.

These delays do not have any impact on the validity of EC certificates to Directive 93/42/EEC, Annex II, Annex V or Annex VI.

Kind regards


Cindy Junge
Customer Service