



To whom it might concern,

We, herewith confirm that the QuantiFERON-TB Gold Plus product line has a self-declared CE mark under the IVD Directive 98/79/EC.

The devices are not defined as high-risk (Annex II, List A/B) and do not require further EC certification.

Manufacturer ISO 13485 certification and EU an declaration of conformity are available upon request.

QIAGEN GmbH  
QIAGEN STRASSE 1  
40724  
HILDEN  
GERMANY

Yours Faithfully,

A handwritten signature in black ink, appearing to read "SH", is written over a light blue horizontal line.

Samuel Hughes  
Senior Specialist, Regulatory Affairs

Date: 03-Apr-2020