



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.

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Yours Faithfully,

Samuel Hughes
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