



EC DECLARATION OF CONFORMITY

ImmuneTICS® C6 Lyme ELISA™ kit
Product Code: DK-E601-096/DK-E601-096-A

We: ImmuneTICS Inc.,

**Address: 320 Norwood Park South, Norwood,
MA 02062, USA**

Declare on our own responsibility that the *in vitro* diagnostic device: the ImmuneTICS C6 Lyme ELISA kit meets the essential requirements of the EC Council Directive 98/79/EC and is in accordance with the relevant requirements of Annex I and III of the IVD Directive.

Declare to fulfil the obligations imposed by Annex III section 2 to 5:

- Availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

ImmuneTICS has a certified Quality Management System in place based on the ISO13485:2003 and I.S EN ISO 13485:2012 standards. This has been certified by National Standards Authority of Ireland (NSAI).

Signed by the Company's designated representative;

A handwritten signature in black ink, appearing to read "J Hughes".

Name: Jon Hughes Ph.D., FTOPRA
Position: VP, Regulatory Affairs & Quality Assurance

Date: 4 December 2018

Authorized Representative established within the EU who has been empowered to enter into commitments on our behalf;

European Authorized Representative (E.A.R.)
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