

## EU Declaration of Conformity



We hereby declare that the product described below conforms to all applicable requirements of Council Directive 98/79/EC for in vitro diagnostic medical devices.

**Legal Manufacturer:** Siemens Healthcare Diagnostics Products Ltd.  
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**Place of Manufacture:** Siemens Healthcare Diagnostics Products Ltd.  
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**EU Authorized Representative:** Siemens Healthcare Diagnostics Manufacturing Ltd.  
Chapel Lane  
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**Product Name:** IMMULITE 3gAllergy Specific IgE Positive Control for MC6L Module

**Catalogue Number (REF):** MC6LCM

**Siemens Material Number (SMN):** 10485106

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 3gAllergy Specific IgE Positive Control for MC6L Module  
MC6LCM

**Version:** 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
This declaration supersedes any declaration issued previously for the same product.*

**Signature:** \_\_\_\_\_ 2019-02-27

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**Date**  
[YYYY-MM-DD]