

## 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.  
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Swords, Co. Dublin, Ireland

**Product Name:** IMMULITE 2000 3g Allergy Specific IgE Universal Kit

**Catalogue Number (REF):** L2KUN6

**Siemens Material Number (SMN):** 10380875

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 3g Allergy Specific IgE Universal Kit L2KUN

**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:**

**Robak  
Malgorzata**

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EU DECLARATION OF CONFORMITY