

## EU Declaration of Conformity



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

EU DECLARATION OF CONFORMITY

**Legal Manufacturer:** Siemens Healthcare Diagnostics Products Ltd.  
Glyn Rhonwy  
Llanberis, Gwynedd, LL55 4EL, UK

**Place of Manufacture:** Siemens Healthcare Diagnostics Products Ltd.  
Glyn Rhonwy  
Llanberis, Gwynedd, LL55 4EL, UK

**EU Authorized Representative:** Siemens Healthcare Diagnostics Manufacturing Ltd.  
Chapel Lane  
Swords, Co. Dublin, Ireland

**Product Names:** See *List of Products*

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** DOC\_Drug Allergens

**Version:** 3.0

*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:** \_\_\_\_\_ **2019-02-22**

**Malgorzata Robak**  
**Regulatory Affairs Supervisor**  
**Siemens Healthcare Diagnostics Products Ltd.**  
**Llanberis, Gwynedd, LL55 4EL, UK**

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

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**List of Products**

<b>Product Name</b>	<b>Catalogue Number (REF)</b>	<b>Siemens Material Number (SMN)</b>
Immulate 2000 Penicilloyl G Specific Allergen	C1L2	10385620
Immulate 2000 Ampicillin Specific Allergen	C203L2	10385621
Immulate 2000 Amoxicillin Specific Allergen	C204L2	10385622
Immulate 2000 Penicilloyl V Specific Allergen	C2L2	10385624
Immulate 2000 Insulin Porcine Specific Allergen	C70L2	10385625
Immulate 2000 Insulin,Bovine Specific Allergen	C71L2	10385626
Immulate 2000 Insulin,Human Specific Allergen	C73L2	10385627
Immulate 2000 Gelatin (porcine) Specific Allergen	C74L2	10639219