

## 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\_Parasite 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:** \_\_\_\_\_ **2019-02-28**

**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>
Immulite 2000 Toxocara canis Specific Allergen	P5L2	10360579
Immulite 2000 Ascaris Specific Allergen	P1L2	10386053
Immulite 2000 Anisakis Larvae Specific Allergen	P4L2	10386054