

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_Insect Allergens

Version: 2.0

*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: _____ **2019-02-24**

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

Date
[YYYY-MM-DD]

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Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Honey Bee Venom Specific Allergen	I1L4	10385950
Immulite 2000 Moth Specific Allergen	I8L2	10385965
Immulite 2000 European Hornet Specific Allergen	I75L2	10385964
Immulite 2000 Mediterranean Flour Moth Specific Allergen	I203L2	10385951
Immulite 2000 Horsefly Specific Allergen	I204L2	10385952
Immulite 2000 American Cockroach Specific Allergen	I206L2	10385953
Immulite 2000 White-Faced Hornet Specific Allergen	I2L2	10385955
Immulite 2000 Yellow Jacket Venom Specific Allergen	I3L2	10385956
Immulite 2000 Paper Wasp Venom Specific Allergen	I4L2	10385957
Immulite 2000 Yellow Hornet Specific Allergen	I5L2	10385958
Immulite 2000 Cockroach Specific Allergen	I6L2	10385959
Immulite 2000 Imported Fire Ant Specific Allergen	I70L2	10385960
Immulite 2000 Mosquito Specific Allergen	I71L2	10385961
Immulite 2000 Chironomus spp Specific Allergen	I73L4	10385963