

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.

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_Animal 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: _____ 2019-02-24

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

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Cat Dander - Epithelium Specific Allergen	E1L4	10385642
Immulin 2000 Canary feather Specific Allergen	E201L2	10385643
Immulin 2000 Gerbil Epithelium Specific Allergen	E209L2	10385644
Immulin 2000 Pigeon Feather Specific Allergen	E215L2	10385645
Immulin 2000 Chicken Serum Proteins Specific Allergen	E219L2	10385646
Immulin 2000 Cat Serum Albumin Specific Allergen	E220L2	10370455
Immulin 2000 Dog Serum Albumin Specific Allergen	E221L2	10370456
Immulin 2000 Porcine Serum Albumin Specific Allergen	E222L2	10360580
Immulin 2000 Dog Epithelium Specific Allergen	E2L4	10385648
Immulin 2000 Horse Dander Specific Allergens	E3L4	10385650
Immulin 2000 Cow Dander Specific Allergen	E4L2	10385651
Immulin 2000 Dog Dander Specific Allergen	E5L4	10385653
Immulin 2000 Guinea Pig Epithelium Specific Allergen	E6L2	10385654
Immulin 2000 Goose Feathers Specific Allergen	E70L2	10385655
Immulin 2000 Mouse Epithelium Specific Allergen	E71L2	10385656
Immulin 2000 Mouse Urine Specific Allergen	E72L2	10385657
Immulin 2000 Rat Epithelium Specific Allergen	E73L2	10385658
Immulin 2000 Rat Urine Specific Allergen	E74L2	10385659
Immulin 2000 Rat Serum Proteins Specific Allergen	E75L2	10385660
Immulin 2000 Mouse Serum Proteins Specific Allergens	E76L2	10385661
Immulin 2000 Budgerigar Feathers Specific Allergen	E78L2	10385662
Immulin 2000 Pigeon Droppings Specific Allergen	E7L2	10385663
Immulin 2000 Goat Epithelium Specific Allergen	E80L2	10385664
Immulin 2000 Sheep Epithelium Specific Allergen	E81L2	10385665
Immulin 2000 Rabbit Epithelium Specific Allergen	E82L4	10385667
Immulin 2000 Swine Epithelium Specific Allergen	E83L2	10385668
Immulin 2000 Hamster Epithelium Specific Allergen	E84L2	10385669
Immulin 2000 Chicken Feathers Specific Allergen	E85L2	10385670
Immulin 2000 Duck Feathers Specific Allergen	E86L2	10385671
Immulin 2000 Rat Specific Allergen	E87L2	10385672
Immulin 2000 Mouse Specific Allergen	E88L2	10385673
Immulin 2000 Turkey Feathers Specific Allergen	E89L2	10385674
Immulin 2000 Parrot Feathers Specific Allergen	E91L2	10385675
Immulin 2000 Animal Panel 1 Specific Allergen	EP1L4	10385677
Immulin 2000 Animal Panel 2 Specific Allergen	EP2L4	10368598
Immulin 2000 Animal Panel 70 Specific Allergen	EP70L4	10385679



EU Declaration of Conformity

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Animal Panel 71 Specific Allergen	EP71L4	10385681
Immulite 2000 Animal Panel 72 Specific Allergen	EP72L4	10385683



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***THIS SECTION IS NOT TO BE DISTRIBUTED EXTERNALLY
WITH THE DECLARATION OF CONFORMITY
(RESTRICTED – FOR DOCUMENTATION PURPOSES)***

Revision History

Version Number	Date of Version [YYYY-MM-DD]	Author of Version	Description of Changes
3.0	2019-01-28	Ian Williams	EU Rep address