

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_Mites 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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Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulate 2000 Dermatophagoides pteronyssinus Specific Allergen	D1L4	10385630
Immulate 2000 Blomia tropicalis Specific Allergen	D201L2	10385631
Immulate 2000 Dermatophagoides farinae Specific Allergen	D2L4	10385633
Immulate 2000 Dermatophagoides microceras Specific Allergen	D3L2	10385634
Immulate 2000 Acarus siro Specific Allergen	D70L2	10385635
Immulate 2000 Lepidoglyphus destructor Specific Allergen	D71L2	10385636
Immulate 2000 Tyrophagus putrescentiae Specific Allergen	D72L2	10385637
Immulate 2000 Glycyphagus domesticus Specific Allergen	D73L2	10385638
Immulate 2000 Euroglyphus maynei Specific Allergen	D74L2	10385639
Immulate 2000 Mite Panel 1 Specific Allergen	DP1L4	10385640