

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_Inhalant Panels 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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List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Inhalant Panel 1 Specific Allergen	IP1L4	10385968
Immulite 2000 Inhalant Panel 2 Specific Allergen	IP2L4	10385969
Immulite 2000 Inhalant Panel 3 Specific Allergen	IP3L4	10385970
Immulite 2000 Inhalant Panel 4 Specific Allergen	IP4L4	10371225
Immulite 2000 Inhalant Panel 5 Specific Allergen	IP5L4	10368605
Immulite 2000 Inhalant Panel 6 Specific Allergen	IP6L4	10385972
Immulite 2000 Inhalant Panel 7 Specific Allergen	IP7L4	10385974
Immulite 2000 Inhalant Panel 8 Specific Allergen	IP8L4	10385975
Immulite 2000 Inhalant Panel 9 Specific Allergen	IP9L4	10385976
Immulite 2000 Inhalant Panel 10 Specific Allergen	IP10L4	10385967