

## 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\_Mold 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:**

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

2019-02-28

**Date**  
[YYYY-MM-DD]

# EU Declaration of Conformity

## List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Aspergillus oryzae Specific Allergen	M304L2	10386029
Immulite 2000 Phoma betae Specific Allergen	M13L2	10386014
Immulite 2000 Mold Panel 1 Specific Allergen	MP1L4	10386048
Immulite 2000 Botrytis Cinerea Specific Allergen	M7L2	10386044
Immulite 2000 Aspergillus clavatus Specific Allergen	M312L2	10386034
Immulite 2000 Aspergillus flavus Specific Allergen	M311L2	10386033
Immulite 2000 Trichoderma Viride Specific Allergen	M15L2	10386016
Immulite 2000 Epicoccum purpurascens Specific Allergen	M14L2	10386015
Immulite 2000 Pityrosporum orbiculare Specific Allergen	M70L2	10386043
Immulite 2000 Aspergillus nidulans Specific Allergen	M310L2	10386032
Immulite 2000 Stemphylium Solani Specific Allergen	M88L2	10360577
Immulite 2000 Cladosporium herbarum Specific Allergen	M2L4	10386027
Immulite 2000 fusarium Monilliforme Specific Allergen	M9L2	10386046
Immulite 2000 Rhizopus nigricans Specific Allergen	M11L2	10386012
Immulite 2000 Curvularia lunata Specific Allergen	M16L2	10386017
Immulite 2000 Penicillium notatum Specific Allergen	M1L4	10386019
Immulite 2000 Aspergillus niger Specific Allergen	M207L2	10386023
Immulite 2000 Helminthosporium halodes Specific Allergen	M8L2	10386045
Immulite 2000 Alternaria tenuis Specific Allergen	M6L4	10386042
Immulite 2000 Mucor racemosus Specific Allergen	M4L2	10386038
Immulite 2000 Stemphylium botryosum Specific Allergen	M10L2	10386011
Immulite 2000 Aureobasidium pullulans Specific Allergen	M12L2	10386013
Immulite 2000 Candida albicans Specific Allergen	M5L4	10386040
Immulite 2000 Hormodendrum hordei Specific Allergen	M45L2	10386037
Immulite 2000 Chaetomium globosum Specific Allergen	M208L2	10386024
Immulite 2000 Cephalosporium acremonium Specific Allergen	M202L2	10386020
Immulite 2000 Aspergillus terres Specific Allergen	M309L2	10386031
Immulite 2000 Eurotium Specific Allergen	M300L2	10386028
Immulite 2000 Micropolyspora faeni Specific Allergen	M212L2	10386025
Immulite 2000 Trichosporon pullulans Specific Allergen	M203L2	10386021
Immulite 2000 Ulocladium chartarum Specific Allergen	M204L2	10386022
Immulite 2000 Penicillium brevi-compactum Specific Allergen	M305L2	10386030
Immulite 2000 Aspergillus fumigatus Specific Allergen	M3L4	10386036
Immulite 2000 Trichophyton rubrum Specific Allergen	M205L2	10470187

EU DECLARATION OF CONFORMITY

**EU DECLARATION OF CONFORMITY**