

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_Molecular Allergens

Version: 4.0

*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]

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List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 nCan f 1 Specific Allergen	A174L2	10360570
Immulite 2000 nDer f 1 Specific Allergen	A295L2	10360571
Immulite 2000 nDer f 2 Specific Allergen	A302L2	10360572
Immulite 2000 nAsp r 1 Specific Allergen	A3050L2	10360573
Immulite 2000 nDer p 1 Specific Allergen	A310L2	10360574
Immulite 2000 nDer p 2 Specific Allergen	A316L2	10360575
Immulite 2000 nFel d 1 Specific Allergen	A345L2	10360576
Immulite 2000 rApi m 1 Specific Allergen	A45L2	10368595
Immulite 2000 nPru p 3 Specific Allergen	A603L2	10368596
Immulite 2000 nBet v 1 Specific Allergen	A89L2	10368597
Immulite 2000 nOel e 1 Specific Allergen	A482L2	10370467
Immulite 2000 nArt v 1 Specific Allergen	A753L2	10370468
Immulite 2000 rPru av 1 Specific Allergen	A597L2	10471072
Immulite 2000 rPru av 3 Specific Allergen	A599L2	10471074
Immulite 2000 rPru av 4 Specific Allergen	A600L2	10471075
Immulite 2000 rMal d 4 Specific Allergen	A796L2	10471077
Immulite 2000 rMal d 1 Specific Allergen	A464L2	10483381
Immulite 2000 rBet v 2 Specific Allergen	A127L2	10484690
Immulite 2000 rApi m 2 Specific Allergen	A46L2	10713569
Immulite 2000 rVes v 5 Specific Allergen	A670L2	10713576

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