

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_Tree Allergens IMMULITE 2000

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

2019-03-29

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

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List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Live Oak Specific Allergen	T103L2	10386055
Immulite 2000 Walnut Pollen Specific Allergen	T10L2	10386056
Immulite 2000 Sycamore Specific Allergen	T11L2	10386057
Immulite 2000 Willow Specific Allergen	T12L2	10386058
Immulite 2000 Cottonwood Specific Allergen	T14L2	10386059
Immulite 2000 White Ash Specific Allergen	T15L2	10386060
Immulite 2000 White Pine Specific Allergen	T16L2	10386061
Immulite 2000 Japanese Cedar Specific Allergen	T17L4	10386063
Immulite 2000 Eucalyptus Specific Allergen	T18L2	10386064
Immulite 2000 Acacia Specific Allergen	T19L2	10386065
Immulite 2000 Maple Specific Allergen	T1L2	10386066
Immulite 2000 Spruce Specific Allergen	T201L2	10386067
Immulite 2000 Linden Specific Allergen	T208L2	10386068
Immulite 2000 Horn Beam Specific Allergen	T209L2	10386069
Immulite 2000 Mesquite Specific Allergen	T20L2	10386070
Immulite 2000 Privet Specific Allergen	T210L2	10386071
Immulite 2000 Sweet Gum Specific Allergen	T211L2	10386072
Immulite 2000 Bayberry Sweet Gale Specific Allergen	T218L2	10386073
Immulite 2000 Red Cedar Specific Allergen	T219L2	10386074
Immulite 2000 Melaleuca Specific Allergen	T21L2	10386075
Immulite 2000 Pecan Specific Allergen	T22L2	10386077
Immulite 2000 Italian Cypress Specific Allergen	T23L4	10386079
Immulite 2000 Red Maple Specific Allergen	T27L2	10386080
Immulite 2000 Locust tree Specific Allergen	T280L2	10386081
Immulite 2000 Alder Specific Allergen	T2L4	10386083
Immulite 2000 Arizona Ash Specific Allergen	T33L2	10386084
Immulite 2000 White Bald Cypress Specific Allergen	T37L2	10386085
Immulite 2000 Birch Specific Allergen	T3L4	10386087
Immulite 2000 Brazilian Peppertree Specific Allergen	T401L2	10386088
Immulite 2000 Mastic Tree Specific Allergen	T402L2	10386089
Immulite 2000 Tree of Heaven Specific Allergen	T404L2	10386090
Immulite 2000 Date Palm Specific Allergen	T406L2	10386091
Immulite 2000 White Hickory Specific Allergen	T41L2	10386092
Immulite 2000 Red Oak Specific Allergen	T42L2	10386093
Immulite 2000 Loblolly Pine Specific Allergen	T43L2	10386094
Immulite 2000 Hackberry Specific Allergen	T44L2	10386095

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Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Hazelnut Pollen Specific Allergen	T4L4	10386097
Immulite 2000 Beech Specific Allergen	T5L2	10386098
Immulite 2000 Western Juniper Specific Allergen	T60L2	10386099
Immulite 2000 Mountain Cedar Specific Allergen	T6L2	10386100
Immulite 2000 White Mulberry Specific Allergen	T70L2	10386101
Immulite 2000 Red Mulberry Specific Allergen	T71L2	10386102
Immulite 2000 Queen Palm Specific Allergen	T72L2	10386103
Immulite 2000 Australian Pine Specific Allergen	T73L2	10386104
Immulite 2000 Oak Mix Specific Allergen	T77L2	10386105
Immulite 2000 Oak Specific Allergen	T7L4	10386107
Immulite 2000 Japanese Cypress Specific Allergen	T80L2	10386108
Immulite 2000 Japanese Cypress Specific Allergen	T80L4	10386109
Immulite 2000 Japanese Alder Specific Allergen	T81L2	10386110
Immulite 2000 Mango Tree Specific Allergen	T83L2	10386111
Immulite 2000 Elm Specific Allergen	T8L2	10386112
Immulite 2000 Poplar Specific Allergen	T96L2	10386113
Immulite 2000 Olive Specific Allergen	T9L4	10386115
Immulite 2000 Tree Panel 1 Specific Allergen	TP1L4	10386117
Immulite 2000 Tree Panel 2 Specific Allergen	TP2L4	10386119
Immulite 2000 Tree Panel 3 Specific Allergen	TP3L4	10386120
Immulite 2000 Tree Panel 4 Specific Allergen	TP4L4	10386122
Immulite 2000 Tree Panel 5 Specific Allergen	TP5L4	10386124
Immulite 2000 Tree Panel 6 Specific Allergen	TP6L4	10386126
Immulite 2000 Tree Panel 7 Specific Allergen	TP7L4	10386128
Immulite 2000 Tree Panel 8 Specific Allergen	TP8L4	10386127
Immulite 2000 Tree Panel 9 Specific Allergen	TP9L4	10386130