

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_Weed 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: _____ 2019-03-01

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

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulite 2000 Lambs Quarters Specific Allergen	W10L2	10386131
Immulite 2000 Russian Thistle Specific Allergen	W11L2	10386132
Immulite 2000 Goldenrod Specific Allergen	W12L2	10386133
Immulite 2000 Cocklebur Specific Allergen	W13L2	10386134
Immulite 2000 Rough Pigweed Specific Allergen	W14L2	10386135
Immulite 2000 Scale Specific Allergen	W15I2	10386136
Immulite 2000 Rough Mash Elder Specific Allergen	W16L2	10386137
Immulite 2000 Firebush Specific Allergens	W17L2	10386138
Immulite 2000 Sheep Sorrel Specific Allergen	W18L2	10386139
Immulite 2000 Parietaria officinalis Specific Allergen	W19L4	10386141
Immulite 2000 Common Ragweed Specific Allergen	W1L4	10386143
Immulite 2000 Rape Pollen Specific Allergen	W203L2	10386144
Immulite 2000 Ragweed Mix (Ambrosia spp) Specific Allergen)	W209L2	10386145
Immulite 2000 Nettle Specific Allergen	W20L2	10386146
Immulite 2000 Parietaria judaica Specific Allergen	W21L4	10386148
Immulite 2000 Yellow Dockweed Specific Allergen	W23L2	10386149
Immulite 2000 Spiny Pigweed Specific Allergen	W24L2	10386150
Immulite 2000 Western Ragweed	W2L2	10386151
Immulite 2000 Rabbit Bush Specific Allergen	W36L2	10386152
Immulite 2000 Saltbush Specific Allergens	W37L2	10386153
Immulite 2000 Giant Ragweed Specific Allergen	W3L2	10386154
Immulite 2000 Common sagebrush Specific Allergen	W43L2	10386155
Immulite 2000 Dog Fennel Specific Allergen	W46L2	10386156
Immulite 2000 False Ragweed Specific Allergen	W4L2	10386157
Immulite 2000 Wormwood Specific Allergen	W5L2	10386158
Immulite 2000 Baccharis Specific Allergen	W67L2	10386159
Immulite 2000 Iodine Bush Specific Allergen	W69L2	10386160
Immulite 2000 Mugwort Specific Allergen	W6L4	10386162
Immulite 2000 Wingscale Specific Allergen	W75L2	10386163
Immulite 2000 Ox-eye Daisy Specific Allergen	W7L2	10386164
Immulite 2000 Careless Weed Specific Allergen	W82L2	10386165
Immulite 2000 Dandelion Specific Allergen	W8L2	10386166
Immulite 2000 Japanese hop Specific Allergen	W90L2	10639221
Immulite 2000 English Plantain Specific Allergen	W9L4	10386168
Immulite 2000 Weed Panel 1 Specific AllergenI	WP1L4	10386170
Immulite 2000 Weed Panel 2 Specific Allergen	WP2L4	10386172

EU Declaration of Conformity

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulate 2000 Weed Panel 3 Specific Allergen	WP3L4	10386174
Immulate 2000 Weed Panel 5 Specific Allergen	WP5L4	10386176
Immulate 2000 Weed Panel 6 Specific Allergen	WP6L4	10386178
Immulate 2000 Weed Panel 7 Specific Allergen	WP7L4	10386180