

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_Grass 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: _____ 2019-02-22

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 Johnson Grass Specific Allergen	G10L2	10385904
Immulite 2000 Brome Grass Specific Allergen	G11L2	10385905
Immulite 2000 Cultivated Rye Grass Specific Allergen	G12L4	10385907
Immulite 2000 Velvet Grass Specific Allergen	G13L2	10385908
Immulite 2000 Cultivated Oat Grass Specific Allergen	G14L2	10385909
Immulite 2000 Cultivated Wheat Grass Specific Allergen	G15L2	10385910
Immulite 2000 Meadow Foxtail Grass Specific Allergen	G16L2	10385911
Immulite 2000 Bahia Grass Specific Allergen	G17L2	10385912
Immulite 2000 Sweet Vernal Grass Specific Allergen	G1L2	10385913
Immulite 2000 Cultivated Com Specific Allergen	G20L2	10385914
Immulite 2000 Salt grass Specific Allergen	G20L2	10385915
Immulite 2000 Bermuda Grass Specific Allergen	G2L4	10385917
Immulite 2000 Orchard Grass Specific Allergen	G3L4	10385919
Immulite 2000 Meadow Fescue Specific Allergen	G4L2	10385920
Immulite 2000 Perennial Rye Grass Specific Allergen	G5L4	10385922
Immulite 2000 Timothy Grass Specific Allergen	G6L4	10385924
Immulite 2000 Wild Rye Grass Specific Allergen	G70L2	10385925
Immulite 2000 Canary Grass Specific Allergen	G71L2	10385926
Immulite 2000 Common Reed Grass Specific Allergen	G7L2	10385927
Immulite 2000 June Grass Specific Allergen	G8L4	10385929
Immulite 2000 Red Top Specific Allergen	G9L2	10385930
Immulite 2000 Grass Panel 1 Specific Allergen	GP1L4	10385932
Immulite 2000 Grass Panel 2 Specific Allergen	GP2L4	10385934
Immulite 2000 Grass Panel 3 Specific Allergen	GP3L4	10385936
Immulite 2000 Grass Panel 4 Specific Allergen	GP4L4	10385938
Immulite 2000 Grass Panel 5 Specific Allergen	GP5L4	10635710