

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_Occupational 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: _____ 2019-02-28

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

Date
[YYYY-MM-DD]

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
Immulin 2000 Bromelain Specific Allergen	K202L2	10385977
Immulin 2000 Wool Specific Allergen	K20L2	10385980
Immulin 2000 Maleic Anhydride Specific Allergen	K210L2	10385981
Immulin 2000 Tetrachlorophthalic Anhydride TCPA Specific Allergen	K213L2	10385982
Immulin 2000 Horseradish Peroxidase Specific Allergen	K225L2	10385983
Immulin 2000 Ascorbate Oxidase Specific Allergen	K226L2	10385984
Immulin 2000 Flour Dust Specific Allergen	K301L2	10385985
Immulin 2000 Green Coffee Bean Specific Allergen	K70L2	10385986
Immulin 2000 Castor Bean Specific Allergen	K71L2	10385987
Immulin 2000 Ispaghula Specific Allergen	K72L2	10385988
Immulin 2000 Silk (bombyx) Specific Allergen	K74L2	10385989
Immulin 2000 Isocyanate TDI Specific Allergen	K75L2	10385990
Immulin 2000 Isocyanate MDI Specific Allergen	K76L2	10385991
Immulin 2000 Isocyanate HDI Specific Allergen	K77L2	10385992
Immulin 2000 Formaldehyde Specific Allergen	K80L2	10385993
Immulin 2000 Ficus spp. Specific Allergen	K81L2	10385994
Immulin 2000 Latex Specific Allergen	K82L4	10385996
Immulin 2000 Sunflower Seed Specific Allergen	K84L2	10385998
Immulin 2000 Alpha-amylase (fungal) Specific Allergen	K87L2	10385999
Immulin 2000 Hops Specific Allergen Specific Allergen	K8L2	10386000
Immulin 2000 Occupational Panel 1 Specific Allergen	KP1L4	10386001