

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_Dust 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: _____ **2019-02-24**

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

Date
[YYYY-MM-DD]

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List of Products

| Product Name | Catalogue Number (REF) | Siemens Material Number (SMN) |
|---|-------------------------------|--------------------------------------|
| Immulite 2000 House Dust-Greer Specific Allergen | H1L4 | 10385940 |
| Immulite 2000 House Dust- Hollister-Stier Specific Allergen | H2L4 | 10385942 |
| Immulite 2000 House Dust-Bencard Specific Allergen | H3L2 | 10385943 |
| Immulite 2000 House Dust-Japan Specific Allergen | H6L2 | 10385945 |
| Immulite 2000 Dust panel 1 Specific Allergen | HP1L4 | 10385948 |