

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 Name:	IMMULITE 2000 Total T4
Catalogue Number (REF):	L2KT42 L2KT46
Siemens Material Number (SMN):	10381685 10381664
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 2000 Total T4 L2KT4
Version:	02

*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:	2019-02-04
<u>Malgorzata Robak</u> Regulatory Affairs Supervisor Siemens Healthcare Diagnostics Products Ltd. Llanberis, Gwynedd LL55 4EL, UK	Date [YYYY-MM-DD]