

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 AFP

Catalogue Number (REF): L2KAP2, L2KAP6

Siemens Material Number (SMN): 10381187,10381184

Classification: ANNEX II, List B

Conformity Assessment Route: ANNEX IV

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremberg, Germany
Identification No. 0197

Document Identifier: EC DEC_IMMULITE® 2000 AFP

Version: 04

*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: _____ **2019-07-22**

Malgorzata Robak
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Date
[YYYY-MM-DD]