

SIEMENS

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

Product Name: IMMULITE 2000 AFP

Catalogue Number (REF): L2KAP2
L2KAP6

Siemens Material Number (SMN): 10381187
10381184

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 AFP L2KAP

Version: 01

*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:

Anita Wamplé

Anita Wamplé
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK



Date
[YYYY-MM-DD]

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Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Anti-TPO Ab

Catalogue Number (REF): L2KTO2
L2KTO6

Siemens Material Number (SMN): 10381650
10381649

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Anti-TPO Ab L2KTO

Version: 01

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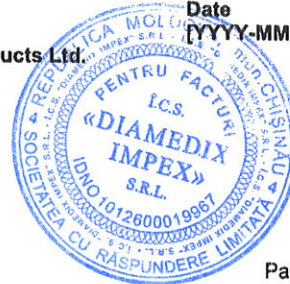
Signature:

Anita Wample

2016-08-24

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

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[YYYY-MM-DD]



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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Anti-HBs

Catalogue Number (REF): L2KAH2

Siemens Material Number (SMN): 10381318

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: Lloyd's Register Quality Assurance Ltd.
1 Trinity Park, Bickenhill Lane
Solihull, B37 7ES, UK
Identification No. 0088

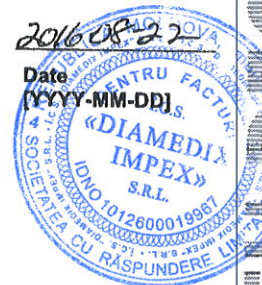
Document Identifier: EC DEC_IMM 2000 Anti-HBs L2KAH

Version: 01

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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Free T4

Catalogue Number (REF): L2KFT42
L2KFT46

Siemens Material Number (SMN): 10381678
10381677

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Free T4 L2KFT4

Version: 01

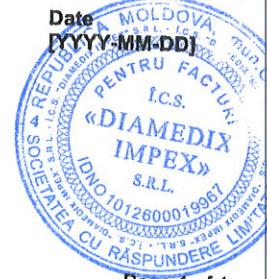
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Signature:

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
LLanberis Gwynedd LL55 4EL, UK

2016-08-22

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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Third Generation TSH

Catalogue Number (REF): L2KTS2

L2KTS6

Siemens Material Number (SMN): 10381665

10381667

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Third Generation TSH L2KTS

Version: 01

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Signature:

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 H. pylori IgG

Catalogue Number (REF): L2KHPG2

L2KHPG6

Siemens Material Number (SMN): 10381336

10381335

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 H. pylori IgG L2KHPG

Version: 01

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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Total T3

Catalogue Number (REF): L2KT32
L2KT36

Siemens Material Number (SMN): 10381654
10381657

Classification: General IVD

Conformity Assessment Route: ANNEX III

Document Identifier: EC DEC_IMM 2000 Total T3 L2KT3

Version: 01

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Signature:

Anita Wample
Head of Quality Management
Siemens Healthcare Diagnostics Products Ltd.
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20160824

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[YYYY-MM-DD]



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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Total T4

Catalogue Number (REF): L2KT42
L2KT46

Siemens Material Number (SMN): 10381685
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Classification: General IVD

Conformity Assessment Route: ANNEX III

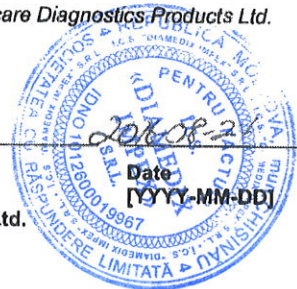
Document Identifier: EC DEC_IMM 2000 Total T4 L2KT4

Version: 01

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Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 PSA

Catalogue Number (REF): L2KPS2
L2KPS6

Siemens Material Number (SMN): 10380986
10380996

Classification: ANNEX II, List B

Conformity Assessment Route: ANNEX IV

Notified Body: Lloyd's Register Quality Assurance Ltd.
1 Trinity Park, Bickenhill Lane
Solihull, B37 7ES, UK
Identification No. 0088

Document Identifier: EC DEC_IMM 2000 PSA L2KPS

Version: 01

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Place of Manufacture: Siemens Healthcare Diagnostics Products Ltd.
Glyn Rhonwy
Llanberis, Gwynedd, LL55 4EL, UK

Product Name: IMMULITE 2000 Anti-HBc IgM

Catalogue Number (REF): L2KMC

Siemens Material Number (SMN): 10381321

Classification: ANNEX II, List A

Conformity Assessment Route: ANNEX IV

Notified Body: Lloyd's Register Quality Assurance Ltd.
1 Trinity Park, Bickenhill Lane
Solihull, B37 7ES, UK
Identification No. 0088

Document Identifier: EC DEC_IMM 2000 Anti-HBc IgM L2KMC

Version: 01

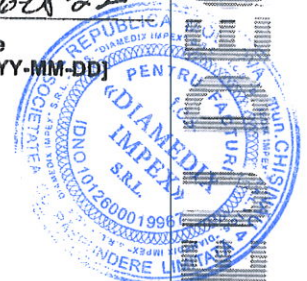
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2016-08-22

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