

## EU Declaration of Conformity



We hereby declare that the product described below conforms 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 Toxoplasma Quantitative IgG

**Catalogue Number (REF):** L2KTXP2

**Siemens Material Number (SMN):** 10381323

**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 Toxoplasma Quantitative IgG L2KTXP

**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:**

**Robak  
Malgorzata**

Digitally signed by Robak Malgorzata  
DN: serialNumber=20020NKF,  
givenName=Malgorzata, sn=Robak, o=Siemens,  
cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.03.05 10:27:52 Z

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

**2019-03-05**

**Date  
[YYYY-MM-DD]**



EU DECLARATION OF CONFORMITY



# SIEMENS

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0088

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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 Toxoplasma IgM ( $\mu$ -Capture)

**Catalogue Number (REF):** L2KTZ2

**Siemens Material Number (SMN):** 10381298

**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 Toxoplasma IgM ( $\mu$ -Capture) L2KTZ

**Version:** 02

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**Signature:**

**Robak  
Malgorzata**

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DN: serialNumber=Z0020NKf,  
givenName=Malgorzata, sn=Robak, o=Siemens,  
cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.03.01 09:46:33 Z

2019-03-01

**Malgorzata Robak  
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Llanberis, Gwynedd, LL55 4EL, UK**

**Date  
[YYYY-MM-DD]**

Document No. EC DEC\_IMM 2000 Toxoplasma IgM ( $\mu$ -Capture) L2KTZ Ver. 02



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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 Testosterone

**Catalogue Number (REF):** L2KTW2  
L2KTW6

**Siemens Material Number (SMN):** 10381190  
10381191

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Total Testosterone L2KTW

**Version:** 02

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**Signature:**

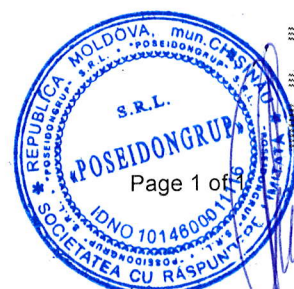
**Robak  
Malgorzata**

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Reason: I am approving this document  
Date: 2019.02.04 14:40:00 Z

**Malgorzata Robak**  
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**Siemens Healthcare Diagnostics Products Ltd.**  
**Llanberis, Gwynedd LL55 4EL, UK**

2019-02-04

Date  
[YYYY-MM-DD]



EU DECLARATION OF CONFORMITY



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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

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**Signature:**

**Robak Malgorzata**

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Reason: I am approving this document  
Date: 2019.02.04 14:34:29 Z

2019-02-04

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

**Date**  
**[YYYY-MM-DD]**



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**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 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:** 02

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**Signature:**

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Date: 2019.02.17 22:18:43 Z

2019-02-17

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

**Date**  
**[YYYY-MM-DD]**



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**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 IgE

**Catalogue Number (REF):** L2KIE2  
L2KIE6

**Siemens Material Number (SMN):** 10380873  
10380872

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Total IgE L2KIE

**Version:** 02

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**Signature:**

**Robak  
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Regulatory Affairs Supervisor  
Siemens Healthcare Diagnostics Products Ltd.  
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Reason: I am approving this document  
Date: 2019.02.01 10:17:48 Z

2019-02-01

**Date  
[YYYY-MM-DD]**





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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 PSA

**Catalogue Number (REF):** L2KPS2, L2KPS6

**Siemens Material Number (SMN):** 10380986, 10380996

**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 PSA

**Version:** 03

*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:** Robak  
Malgorzata

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Date: 2019.09.25 09:58:23 +01'00'

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

2019-09-25

Date  
[YYYY-MM-DD]



EU DECLARATION OF CONFORMITY



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**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 Prolactin

**Catalogue Number (REF):** L2KPR2  
L2KPR6

**Siemens Material Number (SMN):** 10381200  
10381199

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Prolactin L2KPR

**Version:** 02

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Date: 2019.02.17 23:41:42 Z

2019-02-17

Date  
[YYYY-MM-DD]

Document No. EC DEC\_IMM 2000 Prolactin L2KPR Ver. 02



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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.

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Glyn Rhonwy  
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**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 Progesterone

**Catalogue Number (REF):** L2KPW2  
L2KPW6

**Siemens Material Number (SMN):** 10381181  
10381170

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Progesterone L2KPW

**Version:** 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

**Robak Malgorzata**

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sn=Robak, o=Siemens, cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.02.04 14:30:55 Z

2019-02-04

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

**Date**  
**[YYYY-MM-DD]**



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**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 OM-MA

**Catalogue Number (REF):** L2KOP2

**Siemens Material Number (SMN):** 10380972

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 OM-MA L2KOP

**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:** Robak  
Malgorzata

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Reason: I am approving this document  
Date: 2019.02.01 13:05:55 Z

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

**Date**  
2019-02-01  
[YYYY-MM-DD]



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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 LH

**Catalogue Number (REF):** L2KLH2  
L2KLH6

**Siemens Material Number (SMN):** 10381211  
10381212

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 LH L2KLH

**Version:** 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

**Robak Malgorzata**

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Reason: I am approving this document  
Date: 2019.02.01 10:12:38 Z

2019-02-01

**Malgorzata Robak**  
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**Siemens Healthcare Diagnostics Products Ltd.**  
**Llanberis, Gwynedd LL55 4EL, UK**

Date  
[YYYY-MM-DD]



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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 Herpes I & II IgG

**Catalogue Number (REF):** L2KHVG6

**Siemens Material Number (SMN):** 10381333

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Herpes I & II IgG L2KHVG

**Version:** 02

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Reason: I am approving this document  
Date: 2019.02.01 10:21:10 Z

**Malgorzata Robak**  
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**Llanberis, Gwynedd LL55 4EL, UK**

**2019-02-01**

**Date**  
**[YYYY-MM-DD]**



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**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 HBsAg

**Catalogue Number (REF):** L2KHB2

**Siemens Material Number (SMN):** 10381306

**Classification:** ANNEX II, List A

**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 HBsAg

**Version:** 03

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**Signature:**

**Robak  
Malgorzata**

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DN: serialNumber=20020NKF,  
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Reason: I am approving this document  
Date: 2019.09.26 22:54:24 +01'00'

**2019-09-26**

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

**Date  
[YYYY-MM-DD]**



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**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 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:** 02

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**Signature:**

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Malgorzata**

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Regulatory Affairs Supervisor  
Siemens Healthcare Diagnostics Products Ltd.  
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Reason: I am approving this document  
Date: 2019.02.01 10:18:47 Z

2019-02-01

**Date  
[YYYY-MM-DD]**





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**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 GI-MA

**Catalogue Number (REF):** L2KGI2

**Siemens Material Number (SMN):** 10380988

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 GI-MA L2KGI

**Version:** 02

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**Signature:**

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Reason: I am approving this document  
Date: 2019.01.31 15:40:57 Z

2019-01-31

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

Date  
[YYYY-MM-DD]





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**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 FSH

**Catalogue Number (REF):** L2KFS2  
L2KFS6

**Siemens Material Number (SMN):** 10381201  
10381180

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 FSH L2KFS

**Version:** 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

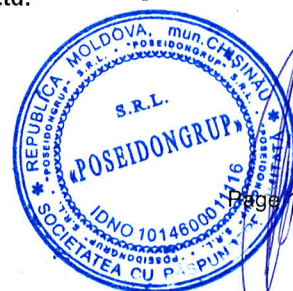
Robak Malgorzata

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DN: serialNumber=20020NKF, givenName=Malgorzata,  
sn=Robak, o=Siemens, cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.01.30 22:42:42 Z

2019-01-30

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

Date  
[YYYY-MM-DD]



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**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 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:** 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:**

Robak Malgorzata

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DN: serialNumber=Z0020WKF,  
givenName=Malgorzata, sn=Robak, o=Siemens,  
cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.01.30 22:40:27 Z

2019-01-30

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

**Date**  
**[YYYY-MM-DD]**



EU DECLARATION OF CONFORMITY

## 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 Anti-TG Ab

**Catalogue Number (REF):** L2KTG2  
L2KTG6

**Siemens Material Number (SMN):** 10381659  
10381655

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Anti-TG Ab L2KTG

**Version:** 02

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**Signature:**

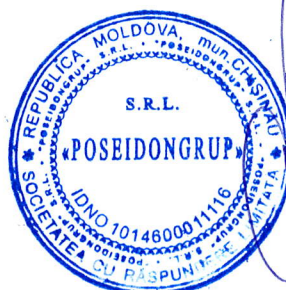
Robak Malgorzata

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Date: 2019.02.04 14:35:36 Z

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

2019-02-04

**Date**  
**[YYYY-MM-DD]**





## 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 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:** 02

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**Signature:**

**Robak  
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**Malgorzata Robak  
Regulatory Affairs Supervisor  
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Reason: I am approving this document  
Date: 2019.02.04 14:37:08 Z

2019-02-04

**Date**  
[YYYY-MM-DD]





## EU Declaration of Conformity



We hereby declare that the product described below conforms 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 Anti-HBc

**Catalogue Number (REF):** L2KHC2

**Siemens Material Number (SMN):** 10381311

**Classification:** ANNEX II, List A

**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 Anti-HBc

**Version:** 03

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

**Robak  
Malgorzata**

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**2019-09-26**

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

**Date  
[YYYY-MM-DD]**



EU DECLARATION OF CONFORMITY

## EU Declaration of Conformity



We hereby declare that the product described below conforms 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 Anti-HBs

**Catalogue Number (REF):** L2KAH2

**Siemens Material Number (SMN):** 10381318

**Classification:** ANNEX II, List A

**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 Anti-HBs

**Version:** 03

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**Signature:**

Robak Malgorzata

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Reason: I am approving this document  
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2019-08-23

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

Date  
[YYYY-MM-DD]



EU DECLARATION OF CONFORMITY

## 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 Thlrd 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 Thlrd Generation TSH L2KTS

**Version:** 02

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**Signature:**

Robak  
Malgorzata

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givenName=Malgorzata, sn=Robak, o=Siemens,  
cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.02.17 22:13:33 Z

2019-02-17

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

Date  
[YYYY-MM-DD]





## 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

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:** Robak  
Malgorzata

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givenName=Malgorzata, sn=Robak, o=Siemens,  
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Reason: I am approving this document  
Date: 2019.07.22 16:07:59 +01'00'

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

2019-07-22

Date  
[YYYY-MM-DD]



## 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 CEA

**Catalogue Number (REF):** L2KCE2  
L2KCE6

**Siemens Material Number (SMN):** 10380994  
10380995

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 CEA L2KCE

**Version:** 02

*This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Products Ltd.  
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**Signature:**

**Robak Malgorzata**

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Reason: I am approving this document  
Date: 2019.01.29 12:34:53 Z

2019-01-29

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

**Date**  
**[YYYY-MM-DD]**



## EU Declaration of Conformity



We hereby declare that the product described below conforms 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 CMV IgG

**Catalogue Number (REF):** L2KCVG2

**Siemens Material Number (SMN):** 10381309

**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 CMV IgG

**Version:** 03

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**Signature:**

**Robak  
Malgorzata**

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givenName=Malgorzata, sn=Robak, o=Siemens,  
cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.09.19 15:02:55 +01'00'

**2019-09-19**

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

**Date  
[YYYY-MM-DD]**





## EU Declaration of Conformity



We hereby declare that the product described below conforms 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 CMV IgM

**Catalogue Number (REF):** L2KCM2

**Siemens Material Number (SMN):** 10381320

**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 CMV IgM

**Version:** 03

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

**Robak Malgorzata**

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DN: serialNumber=20020NKP, givenName=Malgorzata,  
sn=Robak, o=Siemens, cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.08.13 16:24:01 +01'00'

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

**2019-08-13**

**Date**  
**[YYYY-MM-DD]**



## 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 Estradiol

**Catalogue Number (REF):** L2KE22  
L2KE26

**Siemens Material Number (SMN):** 10381178  
10381177

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Estradiol L2KE2

**Version:** 02

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

Robak Malgorzata

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sn=Robak, o=Siemens, cn=Robak Malgorzata  
Reason: I am approving this document  
Date: 2019.01.30 22:10:06 Z

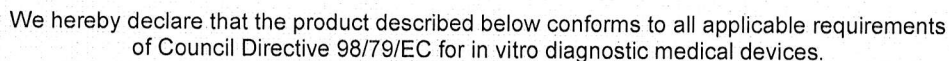
2019-01-30

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

**Date**  
**[YYYY-MM-DD]**



EU DECLARATION OF CONFORMITY



<b>Classification:</b>	ANNEX II, List B
<b>Conformity Assessment Route:</b>	ANNEX IV
<b>Notified Body:</b>	TÜV Rheinland LGA Products GmbH Tillystrasse 2 90431 Nuremberg, Germany Identification No. 0197
<b>Document Identifier:</b>	EC DEC_IMMULITE® 2000 Free PSA
<b>Version:</b>	03

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:**

Robak Malgorzata

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DN: serialNumber=Z0020NKF, givenName=Malgorzata,  
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2019-09-23

**Malgorzata Robak**  
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Siemens Healthcare Diagnostics Products Ltd.  
Llanberis, Gwynedd, LL55 4EL, UK

Date  
[YYYY-MM-DD]



## 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 Free T3

**Catalogue Number (REF):** L2KF32  
L2KF36

**Siemens Material Number (SMN):** 10381675  
10381682

**Classification:** General IVD

**Conformity Assessment Route:** ANNEX III

**Document Identifier:** EC DEC\_IMM 2000 Free T3 L2KF3

**Version:** 02

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This declaration supersedes any declaration issued previously for the same product.*

**Signature:** Robak  
Malgorzata

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Reason: I am approving this document  
Date: 2019.01.30 22:50:39 Z

2019-01-30

**Date**  
[YYYY-MM-DD]

**Malgorzata Robak**  
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