SIEMENS

EU Declaration of Conformity

CE

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/IMMULITE 1000 Rapid TSH
Catalogue Number (REF):	LKRT1 LKRT5
Siemens Material Number (SMN):	10381637 10381628
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Rapid TSH LKRT
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.06 22:51:38 Z

2019-02-06

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

Date [YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

Digitally signed by Marinescu Traian alin
Date: 2023.12.13 15:00:01 EET
Reason: MoldSign Signature
Location: Moldova

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 Total T3
Catalogue Number (REF):	LKT31
Siemens Material Number (SMN):	10381630
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Total T3 LKT3
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun CHISINAU, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967, SOCIETATEA CU RASPUNDERE LIMITATA

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE /IMMULITE 1000 Total T4
Catalogue Number (REF):	LKT41
Siemens Material Number (SMN):	10381633
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Total T4 LKT4
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 Wample 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun CHISINAU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

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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
Product Name:	IMMULITE / IMMULITE 1000 Free T3
Catalogue Number (REF):	LKF31
Siemens Material Number (SMN):	10381626
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Free T3 LKF3
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

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EU Declaration of Conformity

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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
Product Name:	IMMULITE / IMMULITE 1000 Free T4
Catalogue Number (REF):	LKFT41
Siemens Material Number (SMN):	10381622
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Free T4 LKFT4
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 Wample — 2016-08-22

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA mun CHIȘINĂU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE/IMMULITE 1000 Anti-TG Ab
Catalogue Number (REF):	LKTG1
Siemens Material Number (SMN):	10381641
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Anti-TG Ab LKTG
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 Wample — 2016-08-22

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
t.c.s. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
SOCIETATEA CU RASPUNDERE LIMITATA

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 Anti-TPO Ab
Catalogue Number (REF):	LKTO1
Siemens Material Number (SMN):	10381618
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Anti-TPO Ab LKTO
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967
SOCIETATEA CU RASPUNDERE LIMITATA

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE 0088

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/IMMULITE 1000 PSA
Catalogue Number (REF):	LKPS1 LKPS5
Siemens Material Number (SMN):	10380960 10380949
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 1000 PSA LKPS
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 Wample

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

2016-08-19

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE 0088

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
Product Name:	IMMULITE/IMMULITE 1000 Free PSA
Catalogue Number (REF):	LKPF1
Siemens Material Number (SMN):	10380967
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 1000 Free PSA LKPF
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:

REPUBLICA MOLDOVA, mun. CHISINAU, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Anita Wample

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

2016-08-22

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

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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
Product Name:	IMMULITE/IMMULITE 1000 AFP
Catalogue Number (REF):	LKAP1
Siemens Material Number (SMN):	10381162
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 AFP LKAP
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 Wample — 2016-08-22

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

Date
[YYYY-MM-DD]

EU DECLARATION OF CONFORMITY

SIEMENS

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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
Product Name:	IMMULITE / IMMULITE 1000 Cortisol
Catalogue Number (REF):	LKCO1
Siemens Material Number (SMN):	10381388
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Cortisol LKCO
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 Wample for Kevin Owen 2017-03-29

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA mun. CHISINAU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019968 SOCIETATEA CU RASPUNDERE LIMITATA

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 LH
Catalogue Number (REF):	LKLH1
Siemens Material Number (SMN):	10381141
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 LH LKLH
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019961 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 FSH
Catalogue Number (REF):	LKFS1
Siemens Material Number (SMN):	10381153
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 FSH LKFS
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIŞINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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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
Product Name:	IMMULITE / IMMULITE 1000 Total Testosterone
Catalogue Number (REF):	LKTW1
Siemens Material Number (SMN):	10381156
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Total Testosterone LKTW
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA mun. CHISINAU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EC DECLARATION OF CONFORMITY

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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
Product Name:	IMMULITE / IMMULITE 1000 CEA
Catalogue Number (REF):	LKCE1
Siemens Material Number (SMN):	10380945
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 CEA LKCE
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 Wample pp Kevin Owen 2017-03-29

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019867, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

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EU Declaration of Conformity

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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/IMMULITE 1000 GI-MA
Catalogue Number (REF):	LKGI1
Siemens Material Number (SMN):	10380965
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 GI-MA LKGI
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.20 17:39:16 Z

2019-02-20

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

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

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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/IMMULITE 1000 BR-MA
Catalogue Number (REF):	LKBR1
Siemens Material Number (SMN):	10380948
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 BR-MA LKBR
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.19 16:10:36 Z

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

2019-02-19

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

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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/IMMULITE 1000 OM-MA
Catalogue Number (REF):	LKOP1
Siemens Material Number (SMN):	10380969
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 OM-MA LKOP
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.13 23:48:52 Z

2019-02-13

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

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE
0197

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®/IMMULITE 1000 CMV IgG
Catalogue Number (REF):	LKCV1
Siemens Material Number (SMN):	10381289
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®/IMMULITE 1000 CMV IgG
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

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.09.19 15:07:40 +01'00'

2019-09-19

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

Date [YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU * I.C.S. "DIAMEDIX IMPEX" S.R.L. * SOCIETATEA CU RASPUNDERE LIMITATA
I.C.S. «DIAMEDIX IMPEX» S.R.L.
IDNO 1012600019967

SIEMENS

EU Declaration of Conformity

CE 0197

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®/IMMULITE® 1000 CMV IgM
Catalogue Number (REF):	LKCM1
Siemens Material Number (SMN):	10381296
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®/IMMULITE® 1000 CMV IgM
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

Digitally signed by Robak Malgorzata
DN: serialNumber=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.08.13 16:27:32 +01'00'

2019-08-13

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

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 HCG
Catalogue Number (REF):	LKCG1
Siemens Material Number (SMN):	10381161
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 HCG LKCG
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 Wample For Kevin Owen 2017-03-29

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHISINAU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019961 SOCIETATEA CU RASPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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/IMMULITE 1000 Insulin
Catalogue Number (REF):	LKIN1
Siemens Material Number (SMN):	10381429
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Insulin LKIN
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.19 10:11:34 Z

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

2019-02-19

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 Prolactin
Catalogue Number (REF):	LKPR1
Siemens Material Number (SMN):	10381145
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Prolactin LKPR
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 Wample — 2016-08-24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 Calcitonin
Catalogue Number (REF):	LKCL1
Siemens Material Number (SMN):	10381401
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Calcitonin LKCL
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 Wample 2017-03-02

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA. mun. CHISINAU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600016967 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

EC Declaration of Conformity
according to directive 98/79/EC, Annex III

Manufacturer:

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900
U.S.A.

We declare under sole responsibility that the following device to which this declaration relates, meets the essential health and safety requirements and is in conformity with the relevant sections of applicable EC standards and other normative documents. If changes are made to the product which is covered by this declaration of conformity, the declaration of conformity is no longer valid.

Device type:	**In Vitro Diagnostic Medical Device**
Device name:	**IMMULITE® Chemiluminescent Substrate**
Catalog number:	**LSUBX**
National and other standards and technical specifications:	**EN 375, EN 980, ISO 13485, EN 13612, EN 13640, EN 13641, ISO 14971, ISO/IEC 17050-1, 2, EN 17511, 21 CFR 820**
EU Representative:	**Siemens Healthcare Diagnostics Limited** **Faraday House** **Sir William Siemens Square, Frimley** **Camberley, GU16 8QD** **United Kingdom**
Signature/Date of Manufacturer or Responsible Party:	Signature: _____ Date: 8/17/09
Name/Title of Signatory:	Kamdjz Drake (Print Name) — Dir. of QA - Los Angeles (Title)

SIEMENS

Siemens Healthcare Diagnostics Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.	*We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.*

Produktname (deutsch):	***Product name (English):***
IMMULITE Reinigungsmodul	*IMMULITE Probe Cleaning Kit*

Produkt-Nr. / *Product No. (REF):*

LKPM

Packungsgröße(n) / Package Size(s) (REF):

LKPM

IVD-Kategorie / *IVD Category*:

Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	***Address** (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization:*

Director Quality/Regulatory
Unterschrift / *Signature*
Dr. Jörg Amborn
Name /*Name*
2011-04-05
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]*:

REPUBLICA MOLDOVA, mun. CHIŞINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

SIEMENS

Siemens Healthcare Diagnostics
Products GmbH

Konformitätserklärung

Declaration of Conformity

CE

Wir erklären hiermit, dass die unten angegebenen In-vitro-Diagnostika-Produkte mit den Grundlegenden Anforderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates über In-vitro-Diagnostika übereinstimmen und die Anforderungen gemäß Annex III erfüllt werden.	*We hereby declare that the in vitro diagnostic devices described below conforms to all applicable Essential Requirements of Directive 98/79/EC on in vitro Diagnostic Medical Devices and accordance was shown by conformity assessment procedures of Annex III.*

Produktname (deutsch):	***Product name (English):***
IMMULITE Waschmodul	*IMMULITE Probe Wash Module*

Produkt-Nr. / *Product No. (REF):*

LPWS2

Packungsgröße(n) / Package Size(s) (REF):

LPWS2

IVD-Kategorie / *IVD Category*:

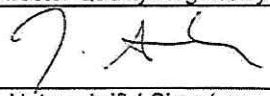
Sonstige	*Others*

Hersteller / *Manufacturer:*

Siemens Healthcare Diagnostics Products GmbH

Adresse (innerhalb Deutschland):	***Address** (international):*
Siemens Healthcare Diagnostics Products GmbH Emil-von-Behring-Str. 76 35041 Marburg	*Siemens Healthcare Diagnostics Products GmbH* *Emil-von-Behring-Str. 76* *35041 Marburg* *Germany*

Bestätigung / *Authorization:*

Director Quality/Regulatory

Unterschrift / *Signature*
Dr. Jörg Amborn
Name /*Name*
2011-04-14
Datum [JJJJ-MM-TT] / *Date [YYYY-MM-DD]:*

SIEMENS

EU Declaration of Conformity

CE

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.

We hereby declare that the products described below are in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment and are in conformity with the harmonised standard EN 50581:2012.

Legal Manufacturer:	Siemens Healthcare Diagnostics Inc. 62 Flanders-Bartley Road Flanders, NJ, 07836, USA
Place of Manufacture:	Caplugs 18704 S. Ferris Place Rancho Dominguez, California, 90220, United States
EC 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_ IMMULITE_LSCC_LSCP
Version:	3.0

This declaration of conformity is issued under the sole responsibility of Siemens Healthcare Diagnostics Inc.
This declaration supersedes any declaration issued previously for the same product.

Signature:

Joseph Ernest

Digitally signed by Joseph Ernest
Date: 2020.10.20 14:19:59 -04'00'

REPUBLICA MOLDOVA, mun. CHIȘINĂU * I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 * SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Ernest Joseph
Director Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
Tarrytown, NY USA

Date
[YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE

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/IMMULITE 1000 Anti-TG Ab
Catalogue Number (REF):	LKTG1
Siemens Material Number (SMN):	10381641
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Anti-TG Ab LKTG
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.10 22:28:55 Z

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

2019-02-10

Date [YYYY-MM-DD]

SIEMENS

EU Declaration of Conformity

CE

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
Product Name:	IMMULITE / IMMULITE 1000 Troponin I
Catalogue Number (REF):	LKTI1
Siemens Material Number (SMN):	10381026
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Troponin I LKTI
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 Wample — 2016.08.24

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

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA, mun. CHIȘINĂU, I.C.S. «DIAMEDIX IMPEX» S.R.L., IDNO 1012600019967, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

CE

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 Names:	See *List of Products*
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM Progesterone LKPW_LPWZ
Version:	2.0

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:

Anita Wample

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

2015-12-11

Date
[YYYY-MM-DD]

REPUBLICA MOLDOVA I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019

EU DECLARATION OF CONFORMITY

EU DECLARATION OF CONFORMITY

SIEMENS

EU Declaration of Conformity

List of Products

Product Name	Catalogue Number (REF)	Siemens Material Number (SMN)
IMMULITE/IMMULITE 1000 Progesterone	LKPW1	10381128 N/A
IMMULITE/IMMULITE 1000 Progesterone Sample Diluent	LPWZ	10388207 N/A

SIEMENS

EU Declaration of Conformity

CE

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/IMMULITE 1000 Vitamin B12
Catalogue Number (REF):	LKVB1
Siemens Material Number (SMN):	10380900
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	EC DEC_IMM 1000 Vitamin B12 LKVB
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=Z0020NKF, givenName=Malgorzata, sn=Robak, o=Siemens, cn=Robak Malgorzata
Reason: I am approving this document
Date: 2019.02.10 22:43:13 Z

2019-02-10

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

Date [YYYY-MM-DD]

MOLDOVA, mun. CHIŞINĂU I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019967 RĂSPUNDERE LIMITATĂ