Formularul ofertei (F3.1)

Data depunerii ofertei: " 20 " noiembrie 2019

Licitaţia Nr.: 2101397

Invitaţie la licitaţia Nr.:

Către: ***IMSP AMT Buiucani.***

ICS Diamedix Impex SRL declară că:

a) Au fost examinate şi nu există rezervări faţă de documentele de atribuire.
b) ***ICS Diamedix Impex SRL*** se angajează să furnizeze/presteze, în conformitate cu documentele de atribuire şi condiţiile stipulate în specificaţiile tehnice şi preţ, următoarele bunuri şi/sau servicii: reagenti si consumabile de laborator.
c) Suma totală a ofertei fără TVA constituie:
710 612,00 lei ***(sapte sute zece mii sase sute doisprezece lei lei 00 bani)***.

d) Suma totală a ofertei cu TVA constituie:
772 920, 96 lei ***(sapte sute saptezeci si doi mii noua sute douazeci lei 96 bani)***.
e) Prezenta ofertă va rămîne valabilă pentru perioada de timp specificată în **FDA4.8.**, începînd cu data-limită pentru depunerea ofertei, în conformitate cu **FDA5.2.**, va rămîne obligatorie şi va putea fi acceptată în orice moment pînă la expirarea acestei perioade;
f) În cazul acceptării prezentei oferte, ***ICS Diamedix Impex SRL*** se angajează să obţină o Garanţie de bună execuţie în conformitate cu **FDA7**, pentru executarea corespunzătoare a contractului de achiziţie publică.
g) Nu sîntem în nici un conflict de interese, în conformitate cu punctul **IPO5.4**.
h) Compania semnatară, afiliaţii sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislaţiei în vigoare sau a regulamentelor cu incidenţă în domeniul achiziţiilor publice, în conformitate cu punctul **IPO5.5**.

Semnat: Turcanu L.Ş.

Nume: ***Dorel Turcanu***

În calitate de: ***Reprezentant vanzari***

Ofertantul: ***I.C.S. " Diamedix Impex" S.R.L.***

Adresa: ***mun. Chisinau, str. 31 august 1989 108/2***

Data: *" 19 " noiembrie 2019*

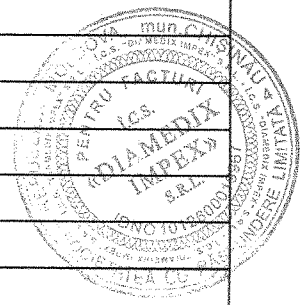
Digitally signed by Marinescu Traian Alin
Date: 2019.11.20 12:10:28 EET
Reason: MoldSign Signature
Location: Moldova

Specificații de preț (F4.2)

[Acest tabel va fi completat de către ofertant în coloanele 5,6,7,8, iar de către autoritatea contractantă – în coloanele 1,2,3,4,9]

Numărul licitației: 21013977	Data: "20" noiembrie 2019		Alternativa nr.: _____
Denumirea licitatiei: Achiziționarea reactivelor de laborator pentru 2020	Lot: _____		Pagina: 1 din 2

Cod CPV	Denumirea bunurilor și/sau a serviciilor	Unitatea de măsură	Canti-tatea	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fara TVA	Suma cu TVA	Termenul de livrare/prestare
1	2	3	4	5	6	7	8	9
33696500-0	AFP	teste	800	37,21	40,19	**29768,00**	**32149,44**	
33696500-0	Anti-HBs	teste	400	30,87	33,34	**12348,00**	**13335,84**	
33696500-0	Anti TG Ab	teste	200	29,00	31,32	**5800,00**	**6264,00**	
33696500-0	Anti-TPO Ab	teste	1000	37,17	40,14	**37170,00**	**40143,60**	
33696500-0	CEA	teste	200	28,40	30,67	**5680,00**	**6134,40**	
33696500-0	CMV IgG	teste	600	45,63	49,28	**27378,00**	**29568,24**	
33696500-0	CMV IgM	teste	600	93,95	101,47	**56370,00**	**60879,60**	
33696500-0	Free T3	teste	400	15,68	16,93	**6272,00**	**6773,76**	
33696500-0	FREE T4	teste	1000	21,02	22,70	**21020,00**	**22701,60**	
33696500-0	GI-MA (CA19-9)	teste	200	47,72	51,54	**9544,00**	**10307,52**	
33696500-0	HBsAg	teste	2800	34,13	36,86	**95564,00**	**103209,12**	
33696500-0	Helicobacter pylori IgG	teste	1400	40,67	43,92	**56938,00**	**61493,04**	
33696500-0	Herpes I & II IgG	teste	200	101,19	109,29	**20238,00**	**21857,04**	
33696500-0	Total Ig E	teste	200	41,66	44,99	**8332,00**	**8998,56**	
33696500-0	PSA	teste	800	30,18	32,59	**24144,00**	**26075,52**	
33696500-0	FREE PSA	teste	200	31,00	33,48	**6200,00**	**6696,00**	
33696500-0	Total T4	teste	600	17,70	19,12	**10620,00**	**11469,60**	
33696500-0	Total T 3	teste	200	19,07	20,60	**3814,00**	**4119,12**	
33696500-0	Toxoplasma Cantitativ IgG	teste	600	44,41	47,96	**26646,00**	**28777,68**	
33696500-0	Toxoplasma Cantitativ IgM	teste	400	61,82	66,77	**24728,00**	**26706,24**	



Cod CPV	Denumirea bunurilor şi/sau a serviciilor	Unitatea de măsură	Canti-tatea	Preţ unitar (fără TVA)	Preţ unitar (cu TVA)	Suma fara TVA	Suma cu TVA	Termenul de livrare/prestare
1	2	3	4	5	6	7	8	9
33696500-0	TSH	teste	2000	15,81	17,07	**31620,00**	**34149,60**	
33696500-0	Solutie spalat Probe L2KPM	set	10	1100,00	1320,00	**11000,00**	**13200,00**	
33696500-0	Spalator Probe dimensiunea L2PWSM	set	8	1500,00	1800,00	**12000,00**	**14400,00**	
33696500-0	Cupe de reactie (Reaction Tubes)	bucati	15000	1,50	1,80	**22500,00**	**27000,00**	
33696500-0	Substrat	set	9	16102,00	17390,16	**144918,00**	**156511,44**	
	Total					**710612,00**	**772920,96**	

Semnat: Turcanu Numele, Prenumele: Dorel Turcanu În calitate de: **Reprezentant vanzari**

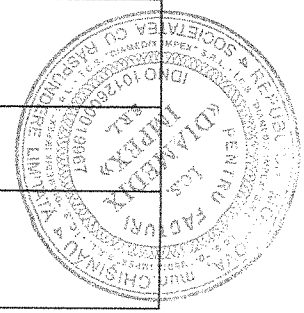
Ofertantul: **I.C.S. "D IAMEDIX IMPEX" S.R.L.** Adresa: **mun. Chisinau, str. 31 august 1989 108/2**

Specificaţii tehnice (F4.1)

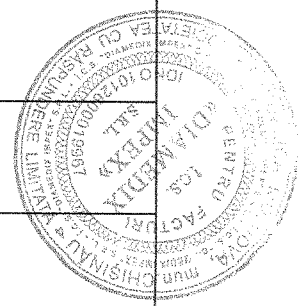
[Acest tabel va fi completat de către ofertant în coloanele 3, 4, 5, 7, iar de către autoritatea contractantă – în coloanele 1, 2, 6, 8]

Numărul licitaţiei:	**21013977**	Data: „20" noiembrie 2019		Alternativa nr.: _____
Denumirea licitaţiei:	**Achizitionarea reactivilor de laborator pentru 2020**	Lot: _____		Pagina: 1 din 1

Cod CPV	Denumirea bunurilor şi/sau a serviciilor	Modelul articolului	Ţara de origine	Produ-cătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referinţă
1	2	3	4	5	6	7	8
	Bunuri/Servicii:						
33696500-0	AFP	L2KAP2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Anti-HBs	L2KAH2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Anti TG	L2KTG2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Anti-TPO Ab	L2KTO2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	CEA	L2KCE2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	CMV IgG	L2KCVG2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	CMV IgM	L2KCM2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Free T3	L2KF32	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	FREE T4	L2KFT42	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	



Cod CPV	Denumirea bunurilor şi/sau a serviciilor	Modelul articolului	Ţara de origine	Produ-cătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referinţă
1	2	3	4	5	6	7	8
	Bunuri/Servicii:						
33696500-0	GI-MA (CA19-9)	L2KGI2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	HBsAg	L2KHB2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Helicobacter pylori IgG	L2KHPG2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Herpes I & II IgG		UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Total Ig E	L2KIE2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	PSA	L2KPS2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Free PSA	L2KPF2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	T4	L2KT42	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	T 3	L2KT32	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Toxoplasma Cantitativ IgG	L2KTXP2	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	Toxoplasma Cantitativ IgM	L2KTZ6	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	
33696500-0	TSH	TSH 3rd Gen.	UK	Siemens Healthcare Diagnostics Products Ltd.	Teste cu calibrator incluşi în set	Teste cu calibrator incluşi în set	



Cod CPV	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Produ-cătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8
	Bunuri/Servicii:						
33696500-0	Solutie spalat Probe dimensiunea	L2KPM	Germania	Siemens Healthcare Diagnostics Products GmbH	Compatibil cu Immulite 2000 XpI	Compatibil cu Immulite 2000 XpI	
33696500-0	Spalator Probe dimensiunea	L2PWSM	Germania	Siemens Healthcare Diagnostics Products GmbH	Compatibil cu Immulite 2000 XpI	Compatibil cu Immulite 2000 XpI	
33696500-0	Cupe de reactie (Reaction Tubes)	REACTION TUBES 1000 PT.2000	U.S.A	Siemens Healthcare Diagnostics Inc.	Compatibil cu Immulite 2000 XpI	Compatibil cu Immulite 2000 XpI	
33696500-0	Substrat	CHEMILUMINI SCENT SUBSTRAT	U.S.A	Siemens Healthcare Diagnostics Inc	Compatibil cu Immulite 2000 XpI	Compatibil cu Immulite 2000 XpI	
	TOTAL						

Semnat: Turcanu Numele, Prenumele: **Turcanu Dorel** În calitate de: **Reprezentant vanzari**

Ofertantul: **I.C.S. "D IAMEDIX IMPEX" S.R.L.** Adresa: **mun. Chisinau, str. 31 august 1989, 108/2**

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 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:	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

Date
[YYYY-MM-DD] 2016-08-22

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 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

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

Date 2016-08-24
[YYYY-MM-DD]

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 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

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

2016-08-22

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.

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 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:	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 Wimple 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]

EU DECLARATION OF CONFORMITY

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 2000 / IMMULITE 2500 Reinigungsmodul	*IMMULITE 2000 / IMMULITE 2500 Probe Cleaning Kit*

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

L2KPM

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

L2KPM

IVD-Kategorie / *IVD Category*:

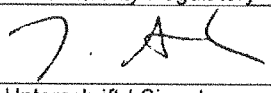
Sonstige	*Others*

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]:*

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 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

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

Date [YYYY-MM-DD] 2016-05-24

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 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

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

2016-08-22

Date [YYYY-MM-DD]

I.C.S. «DIAMEDIX IMPEX» S.R.L.

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 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:	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 2018-08-24

Anita Wample
Head of Quality Management
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 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 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

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

Date [YYYY-MM-DD] 2016-08-20

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 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

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

2016-08-22

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.

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 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:	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:

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

Date
[YYYY-MM-DD] 2017-06-16

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 2000 CMV IgG
Catalogue Number (REF):	L2KCVG2
Siemens Material Number (SMN):	10381309
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 CMV IgG L2KCVG
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

Date [YYYY-MM-DD] 2016.08.22

REPUBLICA MOLDOVA PENTRU FACTURI I.C.S. «DIAMEDIX IMPEX» S.R.L. IDNO 1012600019867 SOCIETATEA CU RASPUNDERE LIMITATA

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 2000 CMV IgM
Catalogue Number (REF):	L2KCM2
Siemens Material Number (SMN):	10381320
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 CMV IgM L2KCM
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]

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

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 2000 Free PSA
Catalogue Number (REF):	L2KPF2
Siemens Material Number (SMN):	10380984
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 Free PSA L2KPF
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

Date 2016-08-22
[YYYY-MM-DD]

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 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:	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

Date [YYYY-MM-DD] 2016-08-22

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 2000 Toxoplasma IgM (μ-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 (μ-Capture) L2KTZ
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

Date [YYYY-MM-DD] 2016-08-22

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 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:	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]

SIEMENS

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
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:	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

2016-08-24

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.

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 Wample

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

Date [YYYY-MM-DD] 2016-08-22

I.C.S. «DIAMEDIX IMPEX» S.R.L.

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
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:	Lloyd's Register Quality Assurance Ltd. 1 Trinity Park, Bickenhill Lane Solihull, B37 7ES, UK Identification No. 0088
Document Identifier:	EC DEC_IMM 2000 HBsAg L2KHB
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: 2019.03.04 10:09:38 Z

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

Date [YYYY-MM-DD] 2019-03-04

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 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

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: 2019.02.01 19:21:10 Z

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

2019-02-01

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 Inc. 62 Flanders-Bartley Road Flanders, NJ, 07836, USA
Place of Manufacture:	CARCLO TECHNICAL PLASTICS Grant Road Tucson, AZ 85705, USA Hoover Precision Products 1390 Industrial Park Dr., Sault Ste. Marie, MI 49783, USA
EC Authorized Representative:	Siemens Healthcare Diagnostics Manufacturing Ltd. Chapel Lane Swords, Co. Dublin, Ireland
Product Name:	IMMULITE 2000 Systems Reaction Tubes
Catalogue Number (REF):	LRXT
Siemens Material Number (SMN):	10385206
Classification:	General IVD
Conformity Assessment Route:	ANNEX III
Document Identifier:	DoC_IMMULITE 2000_RxnTubes
Version:	4.0

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: Ryan Sherrie

Digitally signed by Ryan Sherrie
DN: serialNumber=Z0026ZFR, givenName=Sherrie, sn=Ryan, o=Siemens, cn=Ryan Sherrie
Date: 2019.05.21 09:12:46 -04'00'

Sherrie Ryan
Sr Manager Regulatory Affiars
Siemens Healthcare Diagnostics Inc.
Newark, DE 19714

Date
[YYYY-MM-DD]

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 2000 / IMMULITE 2500 Waschmodul	*IMMULITE 2000 / IMMULITE 2500 Probe Wash Module*

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

L2PWSM

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

L2PWSM

IVD-Kategorie / *IVD Category*:

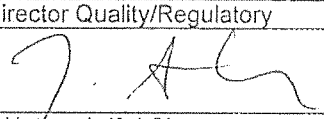
Sonstige	*Others*

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]:*

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® 2000 Chemiluminescent Substrate**
Catalog number:	**L2SUBM**
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) 08/17/09 (Date)

Name/Title of Signatory: Kambiz Drake (Print Name) Dir. QA-Los Angeles (Title)

Ed. 00
August 13, 2009

RA-018-A Eff.Date: 04/08

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 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

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

2016-08-20
Date
[YYYY-MM-DD]

Certificate

Nechit Romulus

In recognition of your commitment to continuous
learning and professional development
you have completed:

IMMULITE 2000® Application Training Course

from July13th to July15th 2009

Aristeidis Kalpias
Instructor

Answers for life.

SIEMENS