COPY Certificate of CE-Registration

MDSS Medical Device Safety Service

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Qualigen, Inc.
2042 Corte del Nogal
CARLSBAD, CA 92009
UNITED STATES OF AMERICA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the *in vitro* diagnostic medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated August 15, 2008

Medical Device Safety Service GmbH (MDSS) has furthermore given notification of the manufacturer's devices to concerned Member State Competent Authorities in accordance with article 10.6 of the *In Vitro* Diagnostic Medical Device Directive 98/79/EC.

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

2008-08-15

Ludger Möller
-President-
MDSS GmbH

Annex A dated August 15, 2008
Manufacturer: Qualigen, Inc.

Notified EDMS Description IVD Medical Device	EDMS Code	Risk Class	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
Testosterone (with Dehydro and Free Testosterone)	12 05 01 10 00	Other	DE/CA09/0170/IVD/1107	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK [1, 2]
FastPack® Testo Immunoassay						
Calibrators Single Component (CC)	11 50 03 02 00	Other	DE/CA09/0170/IVD/1108	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK [1, 2]
FastPack® Testo Calibrator						
Semi-automated I.A. Systems	22 03 02	Other	DE/CA09/0170/IVD/1166	N/A	N/A	AT DK FI DE IS IT MT NO PT RO SI SE CH UK [2]
FastPack® System NP Europe, 20000026 *FastPack® System NP Europe, 20000028* *FastPack® Sample Dispenser Europe, 20000019* *FastPack® Analyzer NP, 08000035, 08000035-X, 08000035-R* *FastPack® Sample Dispenser, 20000028, 08000028-R*						
Total Prostatic Specific Antigen	12 03 01 32 00	Annex II List B	DE/CA09/0170/IVD/1109Ä1	0843/351	2009-06-15	AT DK FI DE IS IT MT NO PT RO SI ES SE CH UK
FastPack® PSA Immunoassay						
Free Prostatic Specific Antigen	12 03 01 33 00	Annex II List B	DE/CA09/0170/IVD/1110Ä1	0843/351	2009-06-15	AT DK FI DE IS IT MT NO PT RO SI ES SE CH UK
FastPack® Free PSA Immunoassay						
Other Specific Control Sera (CC)	11 50 02 90 00	Annex II List B	DE/CA09/0170/IVD/1111Ä1	0843/351	2009-06-15	AT DK FI DE IS IT MT NO PT RO SI ES SE CH UK
FastPack® PSA Controls						

1. Portuguese authoritiy does not require art. 10.6 IVDD notification for this product at this time.
2. Spanish authority does not require art. 10.6 IVDD notification for this product at this time.

Annex A dated August 15, 2008
Manufacturer: Qualigen, Inc.

Notified EDMS Description IVD Medical Device	EDMS Code	Risk Class	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD	Countries Notified
Calibrators Single Component (CC)	11 50 03 02 00	Annex II List B	DE/CA09/0170/IVD/1112Ä1	0843/351	2009-06-15	AT DK FI DE IS IT MT NO PT RO SI ES SE CH UK
FastPack® Total PSA Calibrators						
Free Thyroxine	12 04 01 02 00	Other	DE/CA09/0170/IVD/2682	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK 1. 2.
FastPack® FT4 Immunoassay - 50 Test Kit						
Thyroid Stimulating Hormone	12 04 01 11 00	Other	DE/CA09/0170/IVD/2683	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK 1. 2.
FastPack® TSH Immunoassay - 50 Test Kit						
Human Chorionic Gonadotropin	12 05 02 05 00	Other	DE/CA09/0170/IVD/2684	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK 1. 2.
FastPack® hCG Immunoassay - 50 Test Kit *FastPack® hcg Diluent Kit*						
Hormone Controls	12 50 01 04 00	Other	DE/CA09/0170/IVD/2685	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK 1. 2.
FastPack® TSH Control Kit						
Hormone Standards / Calibrators	12 50 01 04 00	Other	DE/CA09/0170/IVD/2686	N/A	N/A	AT DK FI DE IS IT MT NO RO SI SE CH UK 1. 2.
FastPack® TSH Calibrator Kit *FastPack® FT4 Calibrator Kit* *FastPack® hCG Calibrator Kit*						

1. Portuguese authoritiy does not require art. 10.6 IVDD notification for this product at this time.
2. Spanish authority does not require art. 10.6 IVDD notification for this product at this time.

MDSS
Medical Device Safety Service

MDSS · Schiffgraben 41 · 30175 Hannover, Germany

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Qualigen, Inc.
Attn. Mr. Shishir Sinha
Vice President, Operations
2042 Corte del Nogal
CARLSBAD, CA 92009
UNITED STATES OF AMERICA

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30175 Hannover, Germany

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2008-09-03

Confirmation of CE Notification

Dear Mr. Sinha,

It gives me great pleasure to confirm the registration of the below listed product group(s) with the German Competent Authority. Please note, the registration was performed under § 25 MPG. (MPG - Medizinproduktegesetz). This is the Federal Republic of Germanys' national interpretation of IVDD 98/79/EC. In addition and in accordance with Article 10.6 of the IVDD 98/79/EC, MDSS has forwarded notification of the registrations to the listed competent authorities.

Please note that notifications as per article 10.6 were not sent to Portugal or Spain. The Spanish and Portuguese authorities do not require art. 10.6 notifications for products of the lowest risk class "other" at this time.

EDMS Code	Risk Class	EDMS Description	Countries Notified
12 04 01 02 00	Other	Free Thyroxine	Austria, Denmark, Germany, Finland, Iceland, Italy, Malta, Norway, Romania, Slovenia, Sweden, Switzerland, UK
12 04 01 11 00	Other	Thyroid Stimulating Hormone	"
12 05 02 05 00	other	Human Chorionic Gonadotropin Total	"
12 50 01 04 00	other	Hormone Controls	"
12 50 01 03 00	other	Hormone Standards / Calibrators	"

As requested, we have also notified the authorities of previously registrations as follows.

12 03 01 32 00	List B	Total Prostatic Specific Antigen	Austria, Denmark, Finland, Iceland, Norway, Romania, Slovenia,
12 03 01 33 00	List B	Free Prostatic Specific Antigen	"
11 50 02 90 00	List B	Other Specific Control Sera (CC)	"
11 50 03 02 00	List B	Calibrators Single Component (CC)	"
12 05 01 10 00	other	Testosterone (with Dehydro and Free Testosterone)	"
11 50 03 02 00	other	Calibrators Single Component (CC)	"

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22 03 02	other	Semi-automated I.A. System	Austria, Denmark, Finland, Iceland, Italy, Norway, Romania, Slovenia, Switzerland.

Registration / Notification is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

For your convenience please find enclosed a MDSS Certificate of CE Registration summarizing the registrations as of today.

We wish you a successful product launch in Europe.

Best regards,

Joy Grimm
Medical Device Safety Service GmbH

Country name	codes
Austria	AT
Belgium	BE
Bulgaria	BG
Cyprus	CY
Czech Republic	CZ
Denmark	DK
Estonia	EE
Finland	FI
France	FR
Germany	DE
Greece	GR
Hungary	HU
Iceland	IS
Ireland	IE
Italy	IT
Latvia	LV
Lithuania	LT
Liechtenstein	LI
Luxembourg	LU
Malta	MT
Netherlands	NL
Norway	NO
Poland	PL
Portugal	PT
Romania	RO
Slovakia	SK
Slovenia	SI
Spain	ES
Sweden	SE
Switzerland	CH
United Kingdom	UK