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EC DECLARATION OF CONFORMITY (Annex III)

We, Cellestis Limited, of 1046A Dandenong Road, Carnegie, Victoria 3163, Australia, declare that the *in vitro* diagnostic medical devices in the attached Schedule dated 24 June 2009 meets the applicable provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *In vitro* Diagnostic Medical Devices.

Authorised Representative:

MDSS
Schiffgraben 41
30175 Hannover, Germany
Tel: +49 511 6262 8630

A handwritten signature in blue ink, appearing to be "Dr. Stephen Jones", written over a horizontal line.

Signed:

Dr. Stephen Jones
Chief Technical Officer, Cellestis Limited

Date: 19 October 2009



Schedule of Products covered by this Declaration of Conformity:

REF	Description	Product type according to Directive 98/79/EC	EDMS Product Group	GMDN Product Group
0598-0201	QuantiFERON [®] -TB Gold with liquid antigens	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0594-0201	QuantiFERON [®] -TB Gold ELISA (2-plate kit)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0594-0501	QuantiFERON [®] -TB Gold ELISA (Reference Lab Pack)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0599-0201	QuantiFERON [®] -TB Gold In-Tube kit	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0590-0201	QuantiFERON [®] -TB Gold Blood Collection Tubes (200 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0590-0301	QuantiFERON [®] -TB Gold Blood Collection Tubes (300 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0590-0501	QuantiFERON [®] -TB Gold High Altitude Blood Collection Tubes (200 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0590-0505	QuantiFERON [®] -TB Gold High Altitude Blood Collection Tubes (300 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0597-0201	QuantiFERON [®] -TB Gold Single Patient Pack	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0597-0701	QuantiFERON [®] -TB Gold (Luer / Sarstedt Adapter) Single Patient Pack	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
0598-0201	QuantiFERON [®] -TB Gold Antigens	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0591-0205 (GBO# 454402)	QuantiFERON [®] Nil tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0592-0201 (GBO# 454074)	QuantiFERON [®] -TB Gold TB Antigen tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0593-0201 (GBO# 454075)	QuantiFERON [®] Mitogen tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0591-0501 (GBO# 454415)	QuantiFERON [®] High Altitude Nil tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0592-0501 (GBO# 454413)	QuantiFERON [®] -TB Gold High Altitude TB Antigen tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit
T0593-0501 (GBO# 454414)	QuantiFERON [®] High Altitude Mitogen tubes (100 tubes)	Annex III for professional use only (others)	13 06 01 01 00 Interferon (a/b/y)	30617 Interferon a/b/y kit

GBO: Greiner Bio-One Ref No.

Signed:

Dr. Stephen Jones
Chief Technical Officer, Cellestis Limited

Date: 19 October 2009