CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*27 unit dose single well SSP

Product number: 101.911-96 – including *Taq* polymerase
101.911-96u – without *Taq* polymerase

Lot number: 53R
Expiry date: 2015-April-01
Number of tests: 96
Number of wells per test: 1

Well specifications:

Well No.	Production No.
1	2012-101-01

The specificity of the primer solutions of the kit has been tested against 48 well characterized cell line DNAs.
One additional 3'-primer was tested by separately adding one additional 5'-primer.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-December-21

Approved by:

Åsa Olausson

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*27 unit dose single well
Product number: 101.911-96/96u
Lot number: 53R

Intended use: HLA-B*27 low resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-December-21

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs