101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 13X **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*08 SSP

Product number:	**101.127-12/04 – including *Taq* pol.** **101.127-12u/04u – without *Taq* pol.**
Lot number:	**13X**
Expiry date:	**2017-March-01**
Number of tests:	**12 tests – Product No. 101.127-12/12u** **4 tests – Product No. 101.127-04/04u**
Number of wells per test:	**23+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2014-390-01	9	2010-791-24	17	2010-791-17
2	2012-956-02	10	2010-791-10	18	2014-390-18
3	2014-390-03	11	2010-791-11	19	2012-956-19
4	2010-791-04	12	2014-390-12	20	2010-791-20
5	2010-791-05	13	2014-390-13	21	2010-791-21
6	2010-791-06	14	2010-791-14	22	2010-791-22
7	2014-390-07	15	2012-956-15	23	2014-390-23
8	2010-791-08	16	2010-791-16		

The negative control primer pairs, **Production No. 2014-382-01**, can detect contamination with PCR products diluted 10^{-7}.

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 2014-October-08

Approved by:

Kurin Ahlsson

Production Quality Control

CE
0088

For *In Vitro* Diagnostic Use.

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 13X

Lot-specific information

Declaration of Conformity

Product name:	*Olerup* SSP® DRB1*08
Product number:	101.127-12/04, -12u/04u
Lot number:	13X
Intended use:	DRB1*08 high resolution histocompatibility testing
Manufacturer:	*Olerup* SSP AB Franzengatan 5 SE-112 51 Stockholm, Sweden ***Phone:*** +46-8-717 88 27 ***Fax:*** +46-8-717 88 18

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 13485:2012, 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
2014-October-09

Daniel Malica
Head of QA and Regulatory Affairs