

101.423-06 – including *Taq* polymerase, IFU-01  
101.423-06u – without *Taq* polymerase, IFU-02

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
“Instructions for Use” (IFU)

Lot No.: **50X**

Lot-specific information  
**CERTIFICATE OF ANALYSIS**

**Olerup SSP® HLA-A\*25 SSP**

Product number: 101.423-06 – including *Taq* polymerase  
101.423-06u – without *Taq* polymerase  
Lot number: 50X  
Expiry date: 2017-July-01  
Number of tests: 6  
Number of wells per test: 15+1

**Well specifications:**

Well No.	Production No.	Well No.	Production No.
1	2009-628-01	9	2014-434-09
2	2014-434-02	10	2009-628-10
3	2010-810-03	11	2010-810-11
4	2014-434-04	12	2014-434-12
5	2009-628-05	13	2010-810-13
6	2014-434-06	14	2014-434-14
7	2014-434-07	15	2010-810-15
8	2014-434-08		

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:** 2015-January-30

**Approved by:**

*Karin Mattsson*

**Production Quality Control**

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## Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-A\*25  
**Product number:** 101.423-06/06u  
**Lot number:** 50X

**Intended use:** HLA-A\*25 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, 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  
2015-February-03



Daniel Malica  
Head of QA and Regulatory Affairs