101.628-06 – including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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

Lot No.: 04Y

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*17 SSP

Product number:	**101.628-06 – including *Taq* polymerase** **101.628-06u – without *Taq* polymerase**
Lot number:	**04Y**
Expiry date:	**2017-September-01**
Number of tests:	**6**
Number of wells per test:	**15+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2013-289-01	9	2015-487-09
2	2013-289-02	10	2015-487-10
3	2013-289-03	11	2013-289-11
4	2013-289-04	12	2013-289-12
5	2015-487-05	13	2013-289-13
6	2013-289-06	14	2015-487-14
7	2015-487-07	15	2013-289-15
8	2013-289-08		

The negative control primer pairs, **Production No. 2015-499-01**, 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-April-17

Approved by:

Karin Mattsson

Production Quality Control

101.628-06 – including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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Lot No.: 04Y **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*17
Product number: 101.628-06/06u
Lot number: 04Y

Intended use: HLA-C*17 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 III, 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.

Stockholm, Sweden
2015-April-20

Daniel Malica
Head of QA and Regulatory Affairs