104.201-12 – including *Taq* polymerase
104.201-12u – without *Taq* polymerase

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

Lot No.: 7G7   Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® KIR HLA Ligand
Product number: 104.201-12/12u
Lot number: 7G7

Intended use: Determination of HLA-A^{Bw4+}, HLA-B^{Bw4+}, HLA-B^{Bw6+} and HLA-C KIR ligand sequence motifs.

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 EN 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

2018103 1

Emil Jonsson
Head of QA

CE

October 2018
Rev. No.: 00

In U.S.: For Research Use Only.
Not For Use in Diagnostic Procedures.

104.201-12 – including *Taq* polymerase   Visit www.olerup.com for
104.201-12u – without *Taq* polymerase   **"Instructions for Use" (IFU)**
Lot No.: **7G7**   Lot-specific information
CERTIFICATE OF ANALYSIS

Olerup SSP® KIR HLA Ligand

Product number:	**104.201-12 – including *Taq* polymerase**
	104.201-12u – without *Taq* polymerase
Lot number:	**7G7**
Expiry date:	**2021-03-01**
Number of tests:	**12**
Number of wells per test:	**7+1**

Well specifications:

Well No.	Production No.
1	2018-962-01
2	2018-962-02
3	2018-962-03
4	2018-962-04
5	2018-962-05
6	2018-962-06
7	2018-962-07

The negative control primer pairs, **Production No. 2018-947-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2018-10-25

Approved by: *Rebecca Salm*

Production Quality Control