CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*04:09N

Product number:	**101.861-12 – including *Taq* polymerase** **101.861-12u – without *Taq* polymerase**
Lot number:	**5F7**
Expiry date:	**2021-09-01**
Number of tests:	**12**
Number of wells per test:	**2+1**

Well specifications:

Well No.	Production No.
1	2017-838-01
2	2017-838-02

The negative control primer pairs, **Production No. 2016-746-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2019-08-19

Approved by: Rebecka Salve

Production Quality Control

CE

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*04:09N
Product number: 101.861-12/12u
Lot number: 5F7

Intended use: HLA-C*04:09N histocompatibility testing

Manufacturer:
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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) EN ISO 13485:2016, 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, Franzéngatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
Date: 2019-08-28

Quality Assurance

Changes in revision R01 compared to R00:
1. The expiration date has been altered due to extension of shelf-life.

CE