**Lot No.: 2H1** **Lot-specific Information**

# CERTIFICATE OF ANALYSIS

## *Olerup* SSP® DR low resolution screening

**Product number:** 101.103-48/12 – including *Taq* pol.
101.103-48u/12u – without *Taq* pol.

**Lot number:** 2H1

**Expiry date:** 2021-08-01

**Number of tests:** 48 tests – Product No. 101.103-48/48u
12 tests – Product No. 101.103-12/12u

**Number of wells per test:** 23 + 1

**Well specifications:**

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|---|---|---|---|---|---|
| 1 | 2018-942-01 | 9 | 2018-942-09 | 17 | 2018-942-17 |
| 2 | 2018-942-02 | 10 | 2018-003-10 | 18 | 2018-003-18 |
| 3 | 2018-003-03 | 11 | 2018-942-11 | 19 | 2018-003-19 |
| 4 | 2018-942-04 | 12 | 2018-942-12 | 20 | 2018-942-20 |
| 5 | 2018-942-05 | 13 | 2018-942-13 | 21 | 2018-003-29 |
| 6 | 2018-942-06 | 14 | 2018-942-14 | 22 | 2018-942-30 |
| 7 | 2018-942-07 | 15 | 2018-942-15 | 23 | 2018-003-31 |
| 8 | 2018-003-08 | 16 | 2018-942-16 | | |

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.

***Approved by:*** Rebecka Selare
2019-02-25

**Production Quality Control**

CE
**0088**
For *In Vitro* Diagnostic Use
MA100 v01 CoA_DoC IVD Annex II List B
Date: February 2019, Rev. No: 00

**Lot No.: 2H1** **Lot-specific Information**

# Declaration of Conformity

**Product name:** *Olerup* SSP® DR low resolution screening
**Product number:** 101.103-48/48u, -12/12u
**Lot number:** 2H1

**Intended use:** DRB1 low resolution histocompatibility testing

**Manufacturer:** *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
***Phone:*** +46-8-508 939 00
***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) EN ISO 13485:2016, 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.

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

Notified Body: Lloyd's Register Quality Assurance Limited, 1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
Date: 2019 02 28

Emil Jonsson
Head of Quality Assurance

CE
**0088**
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Date: February 2019, Rev. No: 00