

101.911-96 – including *Taq* pol., IFU-01
101.911-96u – without *Taq* pol., IFU-02

Visit www.olerup.com for
“Instructions for Use” (IFU)

Lot No.: 2H2

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*27 unit dose single well

Product number: 101.911-96 – including *Taq* polymerase
101.911-96u – without *Taq* polymerase
Lot number: 2H2
Expiry date: 2021-06-01
Number of tests: 96
Number of wells per test: 1

Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1 | 2016-658-01 |

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

Date of approval: 2019-01-08

Approved by:



Production Quality Control

101.911-96 – including *Taq* pol., IFU-01
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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® HLA-B*27 unit dose single well

Product number: 101.911-96/96u

Lot number: 2H2

Intended use: HLA-B*27 low resolution histocompatibility testing


Manufacturer: Olerup SSP AB
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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) ISO 9001:2008 and EN ISO 13485:2012, 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.

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

Stockholm, Sweden


 Emil Jonsson
 Head of QA
 2019 01 08