101.201-48/12– including *Taq* pol., IFU-01
101.201-48u/12u– without *Taq* pol., IFU-02

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

Lot No.: 06Y **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQ low resolution SSP

Product number:	**101.201-48/12 – including *Taq* pol.** **101.201-48u/12u – without *Taq* pol.**
Lot number:	**06Y**
Expiry date:	**2017-August-01**
Number of tests:	**48 tests – Product No. 101.201- 48/48u** **12 tests – Product No. 101.201- 12/12u**
Number of wells per test:	**13+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2015-489-01	9	2015-489-09
2	2015-489-02	10	2015-489-10
3	2015-489-03	11	2015-489-11
4	2015-489-04	12	2015-489-12
5	2015-489-05	13	2015-489-13
6	2015-489-06		
7	2015-489-07		
8	2015-489-08		

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-February-20

Approved by:

Karin Mattsson

Production Quality Control

101.201-48/12– including *Taq* pol., IFU-01
101.201-48u/12u– without *Taq* pol., IFU-02

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"Instructions for Use" (IFU)

Lot No.: 06Y

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQ low resolution
Product number: 101.201-48/48u, -12/12u
Lot number: 06Y

Intended use: DQB1 low 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.

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

Stockholm, Sweden
2015-February-20

Anna Hedlund
Head of R & D