101.532-48– including *Taq* polymerase, IFU-01
101.532-48u – without *Taq* polymerase, IFU-02

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

Lot No.: 16V **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*27 SSP – bulk

Product number:	**101.532-48 – including *Taq* polymerase** **101.532-48u – without *Taq* polymerase**
Lot number:	**16V**
Expiry date:	**2016-January-01**
Number of tests:	**48**
Number of wells per test:	**2**

Well specifications:

Well No.	Production No.
1	2013-283-01
2	2013-283-02

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

Date of approval: 2014-February-05

Approved by:

Production Quality Control

101.532-48– including *Taq* polymerase, IFU-01
101.532-48u – without *Taq* polymerase, IFU-02

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

Lot No.: 16V

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*27 - bulk
Product number: 101.532-48/48u
Lot number: 16V

Intended use: HLA-B*27 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 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, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2014-February-05

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs