101.811-12 – including *Taq* polymerase, IFU-01
101.811-12u – without *Taq* polymerase, IFU-02
Lot No.: 6E4

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

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB4*01:03:01:02N SSP

Product number:	**101.811-12 – including *Taq* polymerase** **101.811-12u – without *Taq* polymerase**
Lot number:	**6E4**
Expiry date:	**2019-06-01**
Number of tests:	**12**
Number of wells per test:	**2+1**

Well specifications:

Well No.	Production No.
1	2013-275-01
2	2013-275-02

The negative control primer pairs, **Production No. 2016-695-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 161227

Approved by:

Production Quality Control

CE
0088

For *In Vitro* Diagnostic Use.

101.811-12 – including *Taq* polymerase, IFU-01
101.811-12u – without *Taq* polymerase, IFU-02
Lot No.: 6E4

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

Declaration of Conformity

Product name: *Olerup* SSP® DRB4*01:03:01:02N
Product number: 101.811-12
Lot number: 6E4

Intended use: DRB4*01:03:01:02N 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 EN ISO 13485:2012, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, 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
2017-Jan-02

Daniel Malica
Head of QA and Regulatory Affairs