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

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5H6 **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:	**5H6**
Expiry date:	**2021-12-01**
Number of tests:	**48**
Number of wells per test:	**2**

Well specifications:

Well No.	Production No.
1	2019-011-01
2	2019-011-02

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

Date of approval: 20190725

Approved by:

Production Quality Control

CE
0088
For *In Vitro* Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: July 2019, Rev. No: 00

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

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5H6

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*27 - bulk
Product number: 101.532-48/48u
Lot number: 5H6

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) 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: 2019-08-12

Quality Assurance

CE
0088
For *In Vitro* Diagnostic Use
MA100 v02 CoA_DoC IVD Annex II List B
Date: July 2019, Rev. No: 00