



EU DECLARATION OF CONFORMITY

Manufacturer Name: CareDx AB

Manufacturer Address: Franzéngatan 5
SE-112 51 Stockholm
Sweden

Name of Device: Olerup SSP®, details on pages 2 to 4

Device Item Numbers: See pages 2 to 4

Classification: IVD Annex II, List B

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
Identification Number: 0197

We hereby declare under our sole responsibility that the device specified above meets the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

- *EN ISO 13485: Medical Devices–Quality Management Systems–Requirements for Regulatory Purposes (2016)*
- *EN ISO 14971: Medical Devices- Application of Risk Management to Medical Devices (2012).*
- *EN 62366-1:Medical Devices- Application of Usability Engineering to Medical Devices (2015).*
- *EN ISO 18113-1: In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)- Part 1:Terms, definitions and general requirements (2011).*
- *EN ISO 18113-2: In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)- Part 2: In vitro diagnostic reagents for professional use (2011).*
- *EN ISO 15223-1: Medical Devices - Symbols to be Used With Medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements (2016).*
- *EN 13612: Performance Evaluation of In Vitro Diagnostic Medical Devices (2002).*
- *EN ISO 23640: In vitro diagnostic medical devices- evaluation of stability of in vitro diagnostic reagents (2015).*

All supporting documentation is retained at the premises of the manufacturer.

Stockholm, Sweden

Date: 2021-04-22

A handwritten signature in blue ink that reads "Maria Ilar".

Maria Ilar
Head of Regulatory Affairs
CareDx AB



Product group	Name of Device	Device Item Numbers
SSP	DR low	101.101-12
SSP	DR low	101.101-12U
SSP	DR low	101.101-48
SSP	DR low	101.101-48u
SSP	DR low Screening	101.103-12
SSP	DR low Screening	101.103-12U
SSP	DR low Screening	101.103-48
SSP	DR low Screening	101.103-48U
SSP	DRB1*01	101.111-06
SSP	DRB1*01	101.111-06U
SSP	DRB1*01	101.111-24
SSP	DRB1*01	101.111-24U
SSP	DRB1*03	101.113-04
SSP	DRB1*03	101.113-04u
SSP	DRB1*03	101.113-24
SSP	DRB1*03	101.113-24u
SSP	DRB1*04	101.114-03
SSP	DRB1*04	101.114-03U
SSP	DRB1*04	101.114-24
SSP	DRB1*04	101.114-24U
SSP	DRB1*11	101.115-03
SSP	DRB1*11	101.115-03u
SSP	DRB1*11	101.115-24
SSP	DRB1*11	101.115-24u
SSP	DRB1*13	101.116-03
SSP	DRB1*13	101.116-03u
SSP	DRB1*13	101.116-24
SSP	DRB1*13	101.116-24U
SSP	DRB1*14	101.117-03
SSP	DRB1*14	101.117-03u
SSP	DRB1*14	101.117-12
SSP	DRB1*14	101.117-12u
SSP	DRB1*07	101.118-24
SSP	DRB1*07	101.118-24U
SSP	DRB1*09	101.120-06
SSP	DRB1*09	101.120-06U
SSP	DRB3	101.121-04
SSP	DRB3	101.121-04U
SSP	DRB3	101.121-24
SSP	DRB3	101.121-24U
SSP	DRB4	101.122-06
SSP	DRB4	101.122-06U
SSP	DRB4	101.122-24

Product group	Name of Device	Device Item Numbers
SSP	DRB4	101.122-24U
SSP	DRB5	101.123-06
SSP	DRB5	101.123-06u
SSP	DRB5	101.123-24
SSP	DRB5	101.123-24U
SSP	DRB1*15	101.125-06
SSP	DRB1*15	101.125-06u
SSP	DRB1*15	101.125-24
SSP	DRB1*15	101.125-24U
SSP	DRB1*16	101.126-12
SSP	DRB1*16	101.126-12U
SSP	DRB1*08	101.127-04
SSP	DRB1*08	101.127-04U
SSP	DRB1*08	101.127-12
SSP	DRB1*08	101.127-12U
SSP	DRB1*12	101.128-12
SSP	DRB1*12	101.128-12U
SSP	DRB1*10	101.129-06
SSP	DRB1*10	101.129-06U
SSP	HLA-A low	101.401-12
SSP	HLA-A low	101.401-12u
SSP	HLA-A low	101.401-48
SSP	HLA-A low	101.401-48U
SSP	HLA-A low Screening	101.403-12
SSP	HLA-A low Screening	101.403-12U
SSP	HLA-A low Screening	101.403-48
SSP	HLA-A low Screening	101.403-48U
SSP	HLA-A*01	101.411-06
SSP	HLA-A*01	101.411-06U
SSP	HLA-A*01	101.411-24
SSP	HLA-A*01	101.411-24U
SSP	HLA-A*02	101.412-04
SSP	HLA-A*02	101.412-04u
SSP	HLA-A*02	101.412-24
SSP	HLA-A*02	101.412-24U
SSP	HLA-A*03	101.413-04
SSP	HLA-A*03	101.413-04u
SSP	HLA-A*03	101.413-24
SSP	HLA-A*03	101.413-24U
SSP	HLA-A*11	101.416-04
SSP	HLA-A*11	101.416-04U
SSP	HLA-A*11	101.416-12
SSP	HLA-A*11	101.416-12U



Product group	Name of Device	Device Item Numbers
SSP	HLA-A*68	101.418-04
SSP	HLA-A*68	101.418-04U
SSP	HLA-A*68	101.418-12
SSP	HLA-A*68	101.418-12u
SSP	HLA-A*36	101.419-06
SSP	HLA-A*36	101.419-06u
SSP	HLA-A*23	101.421-06
SSP	HLA-A*23	101.421-06u
SSP	HLA-A*24	101.422-03
SSP	HLA-A*24	101.422-03U
SSP	HLA-A*24	101.422-24
SSP	HLA-A*24	101.422-24U
SSP	HLA-A*25	101.423-06
SSP	HLA-A*25	101.423-06U
SSP	HLA-A*26	101.424-12
SSP	HLA-A*26	101.424-12U
SSP	HLA-A*34	101.425-06
SSP	HLA-A*34	101.425-06U
SSP	HLA-A*66	101.427-06
SSP	HLA-A*66	101.427-06U
SSP	HLA-A*29	101.428-12
SSP	HLA-A*29	101.428-12U
SSP	HLA-A*30	101.429-12
SSP	HLA-A*30	101.429-12U
SSP	HLA-A*31	101.430-12
SSP	HLA-A*31	101.430-12U
SSP	HLA-A*32	101.431-12
SSP	HLA-A*32	101.431-12u
SSP	HLA-A*33	101.432-12
SSP	HLA-A*33	101.432-12U
SSP	HLA-A*74	101.433-06
SSP	HLA-A*74	101.433-06U
SSP	HLA-A*80	101.434-06
SSP	HLA-A*80	101.434-06U
SSP	HLA-A*69	101.435-06
SSP	HLA-A*69	101.435-06u
SSP	HLA-B low	101.501-12
SSP	HLA-B low	101.501-12U
SSP	HLA-B low	101.501-48
SSP	HLA-B low	101.501-48U
SSP	HLA-B low Screening	101.503-12
SSP	HLA-B low Screening	101.503-12U

Product group	Name of Device	Device Item Numbers
SSP	HLA-B low Screening	101.503-48
SSP	HLA-B low Screening	101.503-48U
SSP	HLA-B*07	101.512-03
SSP	HLA-B*07	101.512-03u
SSP	HLA-B*07	101.512-24
SSP	HLA-B*07	101.512-24u
SSP	HLA-B*08	101.513-04
SSP	HLA-B*08	101.513-04u
SSP	HLA-B*08	101.513-24
SSP	HLA-B*08	101.513-24u
SSP	HLA-B*13	101.515-12
SSP	HLA-B*13	101.515-12U
SSP	HLA-B*15	101.516-04
SSP	HLA-B*15	101.516-04U
SSP	HLA-B*15	101.516-24
SSP	HLA-B*15	101.516-24U
SSP	HLA-B*18	101.519-12
SSP	HLA-B*18	101.519-12U
SSP	HLA-B*27 high	101.521-04
SSP	HLA-B*27 high	101.521-04u
SSP	HLA-B*27 high	101.521-24
SSP	HLA-B*27 high	101.521-24u
SSP	HLA-B*35	101.522-03
SSP	HLA-B*35	101.522-03u
SSP	HLA-B*35	101.522-24
SSP	HLA-B*35	101.522-24u
SSP	HLA-B*40	101.523-03
SSP	HLA-B*40	101.523-03U
SSP	HLA-B*40	101.523-24
SSP	HLA-B*40	101.523-24U
SSP	HLA-B*14	101.524-12
SSP	HLA-B*14	101.524-12u
SSP	HLA-B*27 unit dose	101.531-48
SSP	HLA-B*27 unit dose	101.531-48u
SSP	HLA-B*27 bulk	101.532-48
SSP	HLA-B*27 bulk	101.532-48U
SSP	HLA-B*37	101.541-06
SSP	HLA-B*37	101.541-06u
SSP	HLA-B*41	101.542-06
SSP	HLA-B*41	101.542-06U
SSP	HLA-B*42	101.543-06
SSP	HLA-B*42	101.543-06U



Product group	Name of Device	Device Item Numbers
SSP	HLA-B*46	101.544-06
SSP	HLA-B*46	101.544-06u
SSP	HLA-B*47	101.545-06
SSP	HLA-B*47	101.545-06U
SSP	HLA-B*48	101.546-06
SSP	HLA-B*48	101.546-06U
SSP	HLA-B*49	101.547-06
SSP	HLA-B*49	101.547-06U
SSP	HLA-B*50	101.548-06
SSP	HLA-B*50	101.548-06U
SSP	HLA-B*53	101.549-06
SSP	HLA-B*53	101.549-06U
SSP	HLA-B*67	101.550-06
SSP	HLA-B*67	101.550-06u
SSP	HLA-B*78	101.551-06
SSP	HLA-B*78	101.551-06U
SSP	HLA-B*82	101.552-06
SSP	HLA-B*82	101.552-06U
SSP	HLA-B*81	101.553-06
SSP	HLA-B*81	101.553-06u
SSP	HLA-B*59	101.554-06
SSP	HLA-B*59	101.554-06U
SSP	HLA-B*73	101.555-06
SSP	HLA-B*73	101.555-06u
SSP	HLA-B*51	101.561-03
SSP	HLA-B*51	101.561-03u
SSP	HLA-B*51	101.561-24
SSP	HLA-B*51	101.561-24U
SSP	HLA-B*52	101.562-06
SSP	HLA-B*52	101.562-06U
SSP	HLA-B*44	101.563-03
SSP	HLA-B*44	101.563-03U
SSP	HLA-B*44	101.563-24
SSP	HLA-B*44	101.563-24U
SSP	HLA-B*45	101.564-06
SSP	HLA-B*45	101.564-06U
SSP	HLA-B*38	101.565-12
SSP	HLA-B*38	101.565-12U
SSP	HLA-B*39	101.566-04
SSP	HLA-B*39	101.566-04U
SSP	HLA-B*39	101.566-12
SSP	HLA-B*39	101.566-12U
SSP	HLA-B*57	101.567-12

Product group	Name of Device	Device Item Numbers
SSP	HLA-B*57	101.567-12U
SSP	HLA-B*58	101.568-06
SSP	HLA-B*58	101.568-06U
SSP	HLA-B*54	101.569-06
SSP	HLA-B*54	101.569-06U
SSP	HLA-B*55	101.570-06
SSP	HLA-B*55	101.570-06U
SSP	HLA-B*56	101.571-06
SSP	HLA-B*56	101.571-06U
SSP	HLA-B*5701	101.572-12
SSP	HLA-B*5701	101.572-12U
SSP	A-B-DR	101.701-06
SSP	A-B-DR	101.701-06U
SSP	A-B-DR	101.701-24
SSP	A-B-DR	101.701-24u
SSP	A-B-C	101.702-06
SSP	A-B-C	101.702-06u
SSP	A-B-C	101.702-24
SSP	A-B-C	101.702-24u
SSP	DQ-DR	101.704-12
SSP	DQ-DR	101.704-12U
SSP	DQ-DR	101.704-48
SSP	DQ-DR	101.704-48u
SSP	A-B-DR-DQ	101.708-24
SSP	A-B-DR-DQ	101.708-24u
SSP	DRB4*01:03:01:02N	101.811-12
SSP	DRB4*01:03:01:02N	101.811-12u
SSP	DRB5*01:08N	101.812-12
SSP	DRB5*01:08N	101.812-12u
SSP	DRB1*14:01/14:54	101.813-12
SSP	DRB1*14:01/14:54	101.813-12U
SSP	DRB1*04 Add-On	101.814-12
SSP	DRB1*04 Add-On	101.814-12u
SSP	DRB1*12 Add-On	101.815-12
SSP	DRB1*12 Add-On	101.815-12U
SSP	HLA-B*51:11N	101.851-12
SSP	HLA-B*51:11N	101.851-12u
SSP	HLA-B*07 Add-On	101.852-12
SSP	HLA-B*07 Add-On	101.852-12U
SSP	HLA-B*51/B*52	101.904-24u
SSP	HLA-B*27 single well	101.911-96
SSP	HLA-B*27 single well	101.911-96U