



## EU DECLARATION OF CONFORMITY

**Manufacturer Name:** CareDx AB

**Manufacturer Address:** Franzéngatan 5  
SE-112 51 Stockholm  
Sweden

**Name of Device:** See list on page 2

**Device Item Numbers:** See list on page 2

**Classification:** IVD General

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*
- *EN ISO 14971: Medical Devices- Application of Risk Management to Medical Devices*
- *EN IEC 62304: Medical device software – Software life cycle processes*
- *EN 62366-1: Medical Devices- Application of Usability Engineering to Medical Devices*
- *ISO/IEC 9075-1: Information technology -- Database languages -- SQL -- Part 1: Framework (SQL/Framework)*
- *ISO/IEC 9075-2: Information technology -- Database languages -- SQL -- Part 2: Foundation (SQL/Foundation)*

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	DQ low	101.201-12
SSP	DQ low	101.201-12U
SSP	DQ low	101.201-48
SSP	DQ low	101.201-48u
SSP	DQB1*05	101.211-24
SSP	DQB1*05	101.211-24U
SSP	DQB1*06	101.212-04
SSP	DQB1*06	101.212-04u
SSP	DQB1*06	101.212-24
SSP	DQB1*06	101.212-24U
SSP	DQB1*02	101.213-24
SSP	DQB1*02	101.213-24U
SSP	DQB1*03	101.214-06
SSP	DQB1*03	101.214-06U
SSP	DQB1*03	101.214-24
SSP	DQB1*03	101.214-24U
SSP	DQB1*04	101.215-12
SSP	DQB1*04	101.215-12U
SSP	DQB1 high	101.221-12
SSP	DQB1 high	101.221-12u
SSP	DQA1	101.231-04
SSP	DQA1	101.231-04u
SSP	DQA1	101.231-24
SSP	DQA1	101.231-24u
SSP	DPB1	101.311-04
SSP	DPB1	101.311-04u
SSP	DPB1	101.311-24
SSP	DPB1	101.311-24u
SSP	DPA1	101.331-06
SSP	DPA1	101.331-06u
SSP	DPA1	101.331-24
SSP	DPA1	101.331-24u
SSP	HLA-C low	101.601-12
SSP	HLA-C low	101.601-12U
SSP	HLA-C low	101.601-24
SSP	HLA-C low	101.601-24u
SSP	HLA-C low Screening	101.603-12
SSP	HLA-C low Screening	101.603-12U
SSP	HLA-C low Screening	101.603-24
SSP	HLA-C low Screening	101.603-24U
SSP	HLA-C*03	101.611-12
SSP	HLA-C*03	101.611-12u
SSP	HLA-C*04	101.612-12
SSP	HLA-C*04	101.612-12u
SSP	HLA-C*05	101.613-12
SSP	HLA-C*05	101.613-12U

Product group	Name of Device	Device Item Numbers
SSP	HLA-C*06	101.614-12
SSP	HLA-C*06	101.614-12u
SSP	HLA-C*07	101.615-04
SSP	HLA-C*07	101.615-04u
SSP	HLA-C*07	101.615-24
SSP	HLA-C*07	101.615-24U
SSP	HLA-C*01	101.621-12
SSP	HLA-C*01	101.621-12U
SSP	HLA-C*02	101.622-12
SSP	HLA-C*02	101.622-12U
SSP	HLA-C*08	101.623-12
SSP	HLA-C*08	101.623-12U
SSP	HLA-C*12	101.624-12
SSP	HLA-C*12	101.624-12U
SSP	HLA-C*14	101.625-06
SSP	HLA-C*14	101.625-06U
SSP	HLA-C*15	101.626-12
SSP	HLA-C*15	101.626-12U
SSP	HLA-C*16	101.627-12
SSP	HLA-C*16	101.627-12u
SSP	HLA-C*17	101.628-06
SSP	HLA-C*17	101.628-06u
SSP	HLA-C*18	101.629-06
SSP	HLA-C*18	101.629-06u
SSP	HLA C high	101.707-12
SSP	HLA C high	101.707-12u
SSP	HLA-Cw*04:09N	101.861-12
SSP	HLA-Cw*04:09N	101.861-12U
SSP	DQA1*02,05; DQB1*02,0302	101.903-24
SSP	DQA1*02,05; DQB1*02,0302	101.903-24u
SSP	HLA Wipe test	102.101-01
SSP	HLA Wipe test	102.101-01U
SSP	Negative Control	102.102-01
SSP	Negative Control	102.102-01U
SSP	DNA Size marker	103.202-100
SSP	DNA Size marker	103.202-100U
SSP	DNA Size marker	103.202-500
SSP	DNA Size Marker for short Gels	103.203-100
SSP	DNA Size Marker for short Gels	103.203-500
SSP	KIR Genotyping	104.101-12
SSP	KIR Genotyping	104.101-12u
SSP	KIR Ligand	104.201-12
SSP	KIR Ligand	104.201-12u
QTYPE	QTYPE LC480 II Cal Plate	203.501-01
QTYPE	Optically Clear qPCR Seal	203.502-10
XM-ONE	XM-ONE	ABX100-05