EU Declaration of Conformity

Manufacturer Name:	CareDx AB
Manufacturer Address:	Franzéngatan 5 SE-112 51 Stockholm Sweden
Name of Device:	Olerup QTYPE 11®
Device Item Numbers:	201.701-03, 201.701-10
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: 2021-02-17

Maria Ilar
Head of Regulatory Affairs
CareDx AB