



## EU DECLARATION OF CONFORMITY

**Manufacturer Name:** CareDx AB

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

**Name of Device:** SCORE 6™ Interpretation Software

**Device Identification:** Version 6.1.1.0 and higher

**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: 2021-02-17

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

Maria Ilar  
Head of Regulatory Affairs  
CareDx AB