



EC Declaration of Conformity

Manufacturer name: SOPHiA GENETICS SA

Manufacturer address: La Pièce, 12
1180 Rolle
Switzerland

CHRN (Swiss Single Registration Number): CHRN-MF-20002152

Authorized Representative name: SOPHiA GENETICS SAS

Authorized Representative address: Technopole Izarbel
374 Allée Antoine d'Abbadie
64210 Bidart
France

SRN (Single Registration Number): FR-AR-000022214

Basic UDI-DI: 762228300010A9

Name of the device(s): SOPHiA DDM Dx Hereditary Cancer Solution v1.1

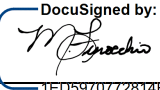
Product codes: BS0102ILLCGLL01-016
BS0102ILLCGLL01-032
BS0102ILLCGLL01-048
BS0102ILLCGLL01-096

Classification: General IVD

Conformity assessment route: EC conformity declaration according to annex III

This declaration of conformity is issued under the sole responsibility of SOPHiA GENETICS SA.
We hereby declare that the medical device(s) specified above meet the provision of the Directive 98/79/EC and Regulation (EU) IVDR 2017/746 article 110(3) for in vitro diagnostic medical devices.
This declaration is supported by the Quality System approval to ISO 13485 issued by BSI.
All supporting documentation is retained at the premises of the manufacturer.

Chief Regulatory Officer
Melissa Finocchio

DocuSigned by:

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Rolle 21/7/2022

Position / Name

Signature

Place

Date

Version	Date	Description
2.0	See DocuSign Signature	Removing typographical error
1.0	19 th May 2022	Creation of the document

Document Approvals

Approved Date: 12 Aug 2022

Approval Task Verdict: Approve	Dawn Little, (DLittle@sophiagenetics.com) Regulatory Approval 12-Aug-2022 14:13:11 GMT+0000
Task: QA Approval Verdict: Approve	Melissa Finocchio, (MFinocchio@sophiagenetics.com) Quality Assurance Approval 12-Aug-2022 14:42:19 GMT+0000