SOPHiA GENETICS
Phone: +41 21 694 10 60
VAT n° / TVA n°: CHE 184.818.745

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:	762228300040AJ
Name of the device(s):	SOPHiA DDM Dx Homologous Recombination Deficiency Solution v1.0
Product code:	BS0121ILLCSMY08-32
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.

Position / Name	Signature	Place	Date
Chief Regulatory Officer Melissa Finocchio	DocuSigned by: 1ED597077281 4ED...	Rolle	21/7/2022

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

Document Approvals

Approved Date: 18 Aug 2022

Approval Task Verdict: Approve	Dawn Little, (DLittle@sophiagenetics.com) Regulatory Approval 03-Aug-2022 14:37:21 GMT+0000

Task: QA Approval Verdict: Approve	Melissa Finocchio, (MFinocchio@sophiagenetics.com) Quality Assurance Approval 18-Aug-2022 16:03:07 GMT+0000