

DECLARATION OF CONFORMITY – HUMAN GENETICS

according to Art. 5 (5) EU Regulation on *in vitro* diagnostic medical devices (EU) 2017/746 (IVDR) for in-house production of IVD in health institutions.

We declare under our sole responsibility that the products listed below and manufactured by in-house production complies with all requirements of the IVD Regulation (EU) 2017/746, Annex I “General Safety and Performance Requirements”, which apply to it. The products was manufactured by us in our own premises on a non-industrial scale and is operated solely in our healthcare institution.

Product code

Information on the in-house devices (also known as laboratory developed tests, LDTs) used (see next page)

Medical Laboratories - Health institution

ARCHIMEDlife GmbH, International Medical Laboratories
located in Leberstrasse 20/2, 1110 Vienna, Austria

Device classification according to Annex VIII:

Class C (see next page)

CEO, Laboratory Director:

Dipl.-Ing. DDr. David C. Kasper

Head of Quality Management:

Andrea Konstantin

Place and date of issue:

Vienna, 13.10.2025

ARCHIMEDlife, a specialty medical laboratory based in Vienna, Austria, provides a wide range of diagnostic services to physicians, healthcare institutions, and private patients. With a strong commitment to medical excellence, ARCHIMEDlife conducts laboratory analyses in areas such as clinical chemistry, immunology, and molecular diagnostics with special focus on rare diseases (www.archimedlife.com).

The laboratory is accredited according to **EN ISO 15189:2022** (with accreditation no. #0407 from the Austrian government – Akkreditierung Austria), ensuring the highest standards of quality, competence, and reliability in medical laboratory services (please see: <https://akkreditierung-austria.gv.at/overview/14451549>)

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Product code, product number	Intended purpose	Risk class	Generic device group (EMDN)
SOP-D03	PCR human genome analysis from isolated nucleic acids GLA	C	W0106010199
SOP-D04	PCR human genome analysis from isolated nucleic acids GAA	C	W0106010199
SOP-D05	PCR human genome analysis from isolated nucleic acids GBA	C	W0106010199
SOP-D07	PCR human genome analysis from isolated nucleic acids SMPD1	C	W0106010199
SOP-D21	Next Generation Sequencing (NGS) human genome analysis for lysosomal storage diseases from isolated nucleic acids	C	W0106010199
SOP-D25	Quantitative determination of SMN1 and SMN2 gene copy number using qPCR from isolated nucleic acids	C	W0106010199
SOP-D32	Next Generation Sequencing (NGS) human genome analysis using TruSight One Panel from isolated nucleic acids	C	W0106010199
SOP-D41	PCR human genome analysis from isolated nucleic acids TTR	C	W0106010199
SOP-D43	Next Generation Sequencing (NGS) human genome analysis for Primary Hyperoxaluria, Porphyria, Amyotrophic Lateral Sclerosis (ALS), and CYP2D6 from isolated nucleic acids	C	W0106010199 W0106030101
SOP-D44	Next Generation Sequencing (NGS) human genome analysis Exome from isolated nucleic acids	C	W0106010199
SOP-D46*	Next Generation Sequencing (NGS) human genome analysis using Amplicon Libraries on PacBio from isolated nucleic acids	C	W0106010199
SOP-D47*	Next Generation Sequencing (NGS) human genome analysis using 65-gene enrichment panel from isolated nucleic acids	C	W0106010199
SOP-D50*	Quantitative determination of CYP2D6 gene copy number using qPCR from isolated nucleic acids	C	W0106030101
SOP-D52*	Next Generation Sequencing (NGS) human genome analysis of WGS (Whole Genome Sequencing) Libraries on PacBio from isolated nucleic acids	C	W0106010199

*fully validated; submitted for accreditation.