ProtaGene

DECLARATION

Under Article 5 (5) EU Regulation on in vitro diagnostic medical devices (EU) 2017/746 (IVDR) for in-house manufacturing of IVDs in health institutions

Name of health institution: ProtaGene CGT GmbH

Address: Im Neuenheimer Feld 582, 69120 Heidelberg, Germany

We declare that the devices described below are manufactured by us through in-house production

Name:	Shearing extension primer tag selection ligation mediated polymerase chain reaction (S-EPTS/LM-PCR)
Type:	Lab Developed Test (LDT)
Version:	2
Unique Device Identifiers (UDI):	4262497420044
Basic UDI-DI:	426249742S-EPTSAB
Device Classification (Annex VIII):	C
Intended Purpose	Shearing extension primer tag selection ligation mediated polymerase chain reaction (S-EPTS/LM-PCR) is a reagent kit intended for the preparation of DNA libraries from human genomic DNA containing lentiviral vector sequences.

And

Name:	GENE-IS Automation Pipeline (GIA)
Type:	Software
Version:	1.2
Unique Device Identifiers (UDI):	4262497420006
Basic UDI-DI:	426249742GIAJA
Device Classification (Annex VIII):	C
Intended Purpose	The aim of this software is to process and analyze viral vector-based gene therapy sequencing data for detecting and estimating the frequency of viral vector integration sites within a cell population treated with gene therapy.

and meet the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746).

The devices were manufactured by ProtaGene within ProtaGene premises and are operated solely within our healthcare institution.

Approvals:

Note: This declaration is electronically signed and considered effective upon final signature (release) in the eQMS.

Author: Person Responsible for Regulatory Compliance (PRRC)

Reviewer: QA

Approver: Managing Director

	Signature	Date
Creation	Dittmann Amanda	05/26/2026 19:14:00 (UTC +1)
Review	Foerster Toni (Dr.)	05/26/2026 19:17:02 (UTC +1)
Release	Stump Michael	05/26/2026 20:01:16 (UTC +1)