Quality Assurance.

Quality standards meet highest demands.

Discover a wide spectrum of DNA analytical products, services and applications that are compliant with globally recognised quality management (QM) and quality assurance (QA) standards.

Eurofins Genomics' products, services and applications reach the best quality and safety levels. They are carried out under strict QM and QA systems and comply with the following standards:

ISO 9001 Globally recognised as the standard quality management certification

ISO 17025 Accredited analytical excellence

ISO 13485 Oligonucleotides according to medical devices standard

GLP The gold standard to conduct non-clinical safety studies

GCP Pharmacogenomic services for clinical studies

cGMP Products and testing according to pharma and biotech requirements

Contact Us.

Toll free phone numbers

Austria	0800 296 562
Belgium	0800 77862
Denmark	8088 1262
Finland	0800 112 744
France	0800 903 807
Ireland	1800 555 056
Italy	800 785 950
Luxemburg	8002 6418
Netherlands	0800 0226215
Norway	800 138 44
Sweden	020 798 148
Switzerland	0800 562 013
UK	0800 0323 135

Email:
support-eu@eurofins.com

Phone:
+49 8092 8289-77

Official business hours:
8 a.m. – 6 p.m. CET

Eurofins Genomics · Anzinger Str. 7 a · 85560 Ebersberg · Germany
eurofinsgenomics.eu

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ISO 13485 CERTIFIED

ISO 13485
General Requirements For Medical Devices.

Scope.

Oligonucleotides according to medical devices standards and directives.

ISO 13485 defines all general requirements for „Medical Devices - Quality Management Systems Requirements“ for regulatory purposes. It applies to manufacturing or assembly of medical devices (MD), of in vitro diagnostic products (IVD) and reagents or substances for use in IVD or MD. QMS (quality management system) requirements are very similar to ISO 9001.

Achieving compliance with European regulatory requirements with ISO 13485

Your benefits with ISO 13485 certified products

- Full documentation and traceability of production processes
- Compliance with regulatory requirements in regard to EU, US and other national directives about medical devices (MD), in vitro diagnostics (IVD) or medicinal products
- ISO 13485 compliant quality management system is in line with the Food and Drug Administration's (FDA) QSR standards

Key Requirements Of ISO 13485.

ISO 13485 focuses strongly on the compliance of manufactured products and production processes with EU directives for MD or IVD such as:

- Provision of technical documentation (medical device file / technical product file)
- Specific design & development requirements
- Labelling, packaging and installation
- Sterile MD / IVD
- Implementation of a risk management process
- Health, safety and staff hygiene requirements
- Change management, market observations and procedures for product recall

ISO 13485
CERTIFIED

The compliance with ISO 13485 is achieved through certification by an approved certification body and independent internal audits.

Applications.

Eurofins Genomics is committed to delivering products, services and applications that are at the highest quality. ISO 13485 is the basic standard for the following applications:

Pharma & Diagnostics

- Manufacturing of medical devices (MD) or in vitro diagnostic products (IVD)
- Manufacturing of reagents or substances for use in IVD or MD

The ISO 13485 standard is applied to the Eurofins Genomics service offering in the field of DNA & RNA oligonucleotides.