

CVI

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Code of the certification body: **1-421-001-086**

Number of the certificate: **SK00 / A0530111M**

This is to certify that the Management System of

HG Pharma GmbH

Hauptstrasse 21, 6365 Kirchberg

is in compliance with the standard

ISO 13485:2016

This Certificate is applicable to the following activities:

**MANUFACTURE OF MEDICAL DEVICES SUBJECT TO THE REGULATORY
REQUIREMENTS OF MDR 745/2017 AND RELEVANT UPDATES.
TRADE IN MEDICAL DEVICES.
PROVIDING SERVICES FOR MEDICAL DEVICES.
PRODUCTION OF IN-VITRO-DIAGNOSTIC, ESPECIALLY
TEST FOR COVID 19.**

System certified from
16/09/2021

Current issue on
16/09/2021

Expiry date
16/09/2024

subject to passing two surveillance audits during 6-12 months and 18-24 months
of the certification.



Ing. Ján Gašper
director

Certification is granted by: **CVI, s.r.o.**, MPCL 3170/31, 058 01 Poprad

For precise and up-to-date information on possible changes in the status of the certification referred to in
this certificate, please call to the number: **+421 944 013365** or e-mail to the address: cvi@cvi.sk

CONFORMANCE VERIFICATION INTERNATIONAL