



Management Systems Certification Body
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
www.itczlin.cz

CERTIFICATE

No. 21 0101 SJ

We confirm on the basis of a performed audit that company

KH Czechia s.r.o.

Vintířovská 1157, 357 35 Chodov, Czech Republic

Company Reg. No.: 27962067

has implemented and documented a functional quality management system
in compliance with the requirements of the standard

ČSN EN ISO 13485 ed. 2:2016

Covering the following activities:

Production of plastic components and assembly of subassemblies for medical
devices

Production of disposable endoscopes

The Certificate is issued on the basis of the results mentioned in Audit Report No. 233405036/2021.
The Certificate validity is conditioned by positive results of surveillance audits, which the certified
company committed to undergo.

During use of the Certificate the Certificate Holder undertakes to follow the Rules of Use of the Certificate. This
document is publicly available on www.itczlin.cz



Date of Issue: 11. 12. 2021

Valid until: 10. 12. 2024

Date of the first certification awarding: 11. 12. 2018


Ing. Pavel Vaněk
Head of Certification Body

CQS z.s.
Prosecká 412/74, 190 00 Praha 9 - Prosek
Czech Republic

CQS is the Certification Body No 3029 accredited according to Standard EN ISO/IEC 17021-1:2015 by the Czech Accreditation Institute for the Certification of Management Systems



CERTIFICATE

No.: CQS 02/2022

CQS certifies that the Quality Management System of

KH Czechia s.r.o.
Vintířovská 1157, 357 35 Chodov, Czech Republic

has been assessed and found to be in conformity with the requirements of

EN ISO 13485:2016

with respect to the following processes; technical areas are presented in the audit report dated 02. 01. 2022

- **Manufacture of plastic components and installation of sub-assemblies for medical devices**
- **Manufacture of disposable endoscopes**

•••••

Expiry date: 01. 01. 2025
Certification decision: 02. 01. 2022
Date of issue: 02. 01. 2022
The first certification: 02. 01. 2019


Jana Olšanská
Managing Director



CQS Members*:

Elektrotechnický zkušební ústav, s.p., Fyzikálně technický zkušební ústav, s.p., Institut pro testování a certifikaci, a.s.,
Strojírenský zkušební ústav, s.p., Technický a zkušební ústav stavební Praha, s.p., Textilní zkušební ústav, s.p.

* A CQS member list valid at the time of issue of the certificate. Current list is available at www.cqs.cz.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CQS has issued an IQNet recognized certificate that the organization:

KH Czechia s.r.o.

Vintířovská 1157, 357 35 Chodov, Czech Republic

has implemented and maintains a

Quality Management System

for the following scope

- *Manufacture of plastic components and installation of sub-assemblies for medical devices*
- *Manufacture of disposable endoscopes*

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: 2022 – 01 – 02

First issued on: 2019 – 01 – 02

Expires on: 2025 – 01 – 01

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: CZ – 02/2022



*Alex Stoichitoiu
President of IQNet*

*Tomáš Hruška
President of CQS*



IQNet Partners*:

*AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com