

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 277/2024

CQS certifies that the Quality Management System of

GAMA GROUP a.s.

Mánesova 11/3b, České Budějovice 7, 370 01 České Budějovice, Czech Republic
Plant: Jimramov, Ubušínská 20, 592 42 Jimramov

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 19. 12. 2024:

**Design and development, production and distribution of medical devices for infusion,
transfusion, venouse pressure measurement, urodynamic, transfer
and priming sets and catheters**

**Services in the field of sterilization of medical devices by the gaseous EO
in keeping with requirements of ČSN EN ISO 11135:2015**

Expiry date: 18. 12. 2027
Certification decision: 19. 12. 2024
Date of issue: 19. 12. 2024


Jana Olšanská
Head of Certification Body



CQS Members*:

Elektrotechnický zkušební ústav, s.p., Fyzikálně technický zkušební ústav, s.p., Institut pro testování a certifikaci, a.s.,
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