



Notified Body No 1023
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EU Quality Management System Certificate No 23 0517 QR/NB

Quality management system of the company

GAMA GROUP a.s.

Mánesova 11/3b, České Budějovice 7, 370 01 České Budějovice, Czech Republic

SRN: CZ-MF-000011894

is certified in accordance with the requirements of

**REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**

on medical devices, Annex IX, Chapters I and III

for the following device-range:

**Infusion sets for gravity feed, Double-ended piercing spike,
Venous pressure meters, Flow regulator infusion**

Notified Body No 1023 declares that it has assessed the quality management system of the above-mentioned manufacturer in accordance with Annex IX, Chapters I and III of the Regulation (EU) 2017/745 for the aspects related to the establishing, securing and maintaining sterile conditions for the device-range covered by this certificate. The audited part of the quality management system complies with the requirements of Regulation (EU) 2017/745 and is subject to regular surveillance audits. A detailed description of the system elements, requirements and measures adopted by the manufacturer is provided in the final report No. 803602913, which is issued together with the present certificate.

Valid from: 2023-11-10

Valid until: 2028-11-09

Previous EU certificate No.: -

Previous EU certificate issue date: -

Date of issue: 2023-11-10



Mgr. Jiří Heš
Representative of Notified Body No 1023