



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

EU Quality Management System Certificate No. 26 0129 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:

Suction catheters, Catheters for neonates, Rectal catheters, GAMAPLUS, Transfer sets, Nasal oxygen introduction catheter, Priming set of dialysis sets, Infusion sets for overpressure infusion, Transfusion sets, Small urodynamic sets, Needleless port, Stopcocks, SKALA OK 3 Perfusion set, Safety valve

Notified Body No. 1023 declares that it has assessed the quality management system of the above manufacturer in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745. The quality management system put in place by the manufacturer for the design, manufacture and final inspection of the products concerned 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. 803602912/2026, which is issued together with the present certificate.

Valid from: 2026-04-30

Valid until: 2031-04-29

Previous EU certificate No.: -
Previous EU certificate issue date: -

Date of issue: 2026-04-30




Mgr. Jiří Heš
Representative of Notified Body No. 1023



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issued to the manufacturer:

GAMA GROUP a.s.
Mánesova 11/3b, České Budějovice 7, 370 01 České Budějovice,
Čzech Republic

Manufacturer details:

Manufacturer's company name: GAMA GROUP a.s.
Single registration number (SRN): CZ-MF-000011894
Registered office address: Mánesova 11/3b, České Budějovice 7, 370 01
České Budějovice, Čzech Republic
Production site address: Závod Jimramov, Ubušínská 20, 592 42
Jimramov část Benátky, Čzech Republic


Details of the authorised representative (if required):

Name of the EU authorised representative: -

Address of the EU authorised representative: -



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Product(s):

Product name: Suction catheters

Trade mark(s): -

Model(s): V606452-M Endobronchial catheter CE – 600 M
V646738-M Suction catheter with CO, 1 BO, 2 mm (Ch 6) x 400 mm M
V646739-M Suction catheter with CO, 1 BO, 2,67 mm (Ch 8) x 400 mm M
V646740-M Suction catheter with CO, 1 BO, 3,33 mm (Ch 10) x 400 mm M
V646741-M Suction catheter with CO, 1 BO, 4 mm (Ch 12) x 400 mm M
V646742-M Suction catheter with CO, 1 BO, 4,67 mm (Ch 14) x 400 mm M
V646743-M Suction catheter with CO, 1 BO, 5,33 mm (Ch 16) x 400 mm M
V646744-M Suction catheter with CO, 1 BO, 6 mm (Ch 18) x 400 mm M
V646745-M Suction catheter with CO, 1 BO, 6,67 mm (Ch 20) x 400 mm M

Class: Ila



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Product(s):


Product name: Catheters for neonates
Trade mark(s): -
Model(s): V646957-M Neonatal nutrition catheter CV-01 M
V646958-M Neonatal umbilical catheter CP-01 M
V646959-M Catheter for neonates of low birth weight CN-01 M
V686417-01M Catheter for neonates CN-01 100 cm M
Class: Ila

Product(s):

Product name: Rectal catheters
Trade mark(s): -
Model(s): V646685-M Rectal catheter with CO, 6,67 mm (Ch 20) x 150 mm M

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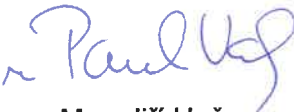
issued to the manufacturer:

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V646686-M Rectal catheter with CO, 6,67 mm (Ch 20) x
200 mm M
V646687-M Rectal catheter with CO, 6,67 mm (Ch 20) x
300 mm M
V646688-M Rectal catheter with CO, 6,67 mm (Ch 20) x
400 mm n
V646696-M Rectal catheter with CO, 10 mm (Ch 30) x
200 mm M
V646697-M Rectal catheter with CO, 10 mm (Ch 30) x
300 mm M
V646698-M Rectal catheter with CO, 10 mm (Ch 30) x
400 mm M
V646699-M Rectal catheter with CO, 4 mm (Ch 12) x
120 mm M
V646700-M Rectal catheter with CO, 4,67 mm (Ch 14) x
120 mm M
V646701-M Rectal catheter with CO, 5,33 mm (Ch 16) x
120 mm M
V646702-M Rectal catheter with CO, 6 mm (Ch 18) x
120 mm M
V646703-M Rectal catheter with CO, 8,3 mm (Ch 25) x
150 mm M

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V646704-M Rectal catheter with CO, 8,3 mm (Ch 25) x
200 mm M

V646705-M Rectal catheter with CO, 8,3 mm (Ch 25) x
300 mm M

V646706-M Rectal catheter with CO, 8,3 mm (Ch 25) x
400 mm M

Class: Ila

Product(s):

Product name: **GAMAPLUS**

Trade mark(s): -

Model(s):

V606301-M GAMAPLUS 1,8 x 450 LL M

V606301-01M GAMAPLUS 1,8 x 450 LLK M

V606303-M GAMAPLUS 1,8 x 1500 LL M

V606304-M GAMAPLUS 1,8 x 1800 LL M

V606304-01M GAMAPLUS 1,8 x 1800 LLK M

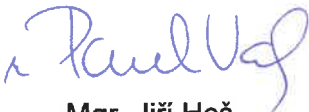
V606306-M GAMAPLUS 1,8 x 450 UNIV M

V606307-M GAMAPLUS 1,8 x 1800 UNIV M

V606321-M GAMAPLUS 3,0 x 150 LL M

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V606342-M GAMAPLUS 3,0 x 300 LL M
V606347-M GAMAPLUS 3,0 x 2500 LL M
V606349-M GAMAPLUS 3,0 x 3500 LL M
V606371-M GAMAPLUS 3,0 x 150 YLL M
V606372-M GAMAPLUS 3,0 x 150 LCH M
V606372-01M GAMAPLUS 4,5 x 20 LCH M
V606502-M 150 cm extension PVC tube M
V686423-M 150 cm extension PVC tube for light-sensitive drugs M
V686423-01M 200 cm extension PVC tube for light-sensitive drugs M
V686423-02M 50 cm extension PVC tube for light-sensitive drugs M
V606402-M Connection Tubing 2-way M
V606404-M Connection Tubing 4-way M
Connection tubing with needleless port M

Class:

Ila



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Product(s):


Product name: Transfer sets
Trade mark(s): -
Model(s): V606386-M Transfer set M
V606386-02M Transfer set PS M
V606386-03M Transfer set PS 61ShA M
Class: Ila

Product(s):

Product name: Nasal oxygen introduction catheter
Trade mark(s): -
Model(s): V646956-M Nasal oxygen introduction catheter CK-472
M
Class: Ila



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Product(s):

Product name: Priming set of dialysis sets
Trade mark(s): -
Model(s): V606003-M Priming set of dialysis sets PS 003 M
Class: Ila

Product(s):

Product name: Infusion sets for overpressure infusion
Trade mark(s): -
Model(s): V606121-M Infusion set IS-121 M
V606123-M Infusion set IS-123 M
V606126-01M Infusion set IS-126 – 62 ShA M
V606126-02M Infusion set IS-126T – 62 ShA M
V606127-M Infusion set IS-127 P M
V606128-M Infusion set IS-127 P 180 cm M
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Product(s):

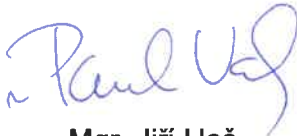
Product name: Transfusion sets
Trade mark(s): -
Model(s): V606203-M Transfusion set TS-203 M
V606204-M Transfusion set TS-204 M
Class: Ila

Product(s):

Product name: Small urodynamic sets
Trade mark(s): -
Model(s): V606481-M Small urodynamic set USM M
V606481-02M Small urodynamic set USM – 1845 mm
M
V606481-03M Small urodynamic set USM – S M
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Product(s):

Product name: Needleless port
Trade mark(s): -
Model(s): V696420-M Needleless port M
V696421-M Needleless port – červený M
Class: Ila

Product(s):

Product name: Stopcocks
Trade mark(s): -
Model(s): V696436-M Ramp - 3 taps NO PVC M
V696437-M Ramp – 5 taps NO PVC M
V696423-M Ramp 3-way with NP NO PVC M
V696425-M Ramp 5-way with NP NO PVC M
V696434-M Three-way tap – red NO PVC M
V696435-M Three-way tap – blue NO PVC M
V696442-M Three-way tap – white NO PVC M
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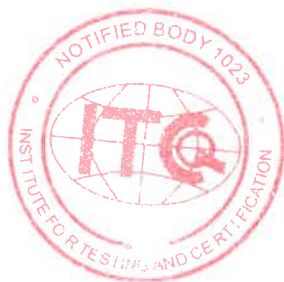
GAMA GROUP a.s.
Mánesova 11/3b, České Budějovice 7, 370 01 České Budějovice,
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Product(s):


Product name: SKALA OK 3 Perfusion set
Trade mark(s): -
Model(s): V606501-M SKALA OK3 Perfusion set M
V606501-01M SKALA OK3-V1 Perfusion set M
V606501-02M SKALA OK3-V2 Perfusion set M
V606501-03M SKALA OK3-V3 Perfusion set M
Class: Ila

Product(s):

Product name: Safety valve
Trade mark(s): -
Model(s): V696433-M Safety valve NO PVC M
Class: Ila



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