

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV



ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHJECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
ЭЛЕКТРОТЕХНИЧЕСКИЙ ИСПЫТАТЕЛЬНЫЙ ИНСТИТУТ - ЧЕШСКАЯ РЕСПУБЛИКА

Pod lisem 129/2, 171 02 Praha 8 - Troja

EC CERTIFICATE FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 210012

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **GAMA GROUP a.s.**
Mánesova 11/3b, 370 01 České Budějovice, Czech Republic

in manufacturing sites **GAMA GROUP a.s.**
Ubušínská 20, 592 42 Jimramov, Czech Republic

for design, manufacturing and final inspection of medical device(s)

**Infusion, transfusion, dialysis and urodynamic sets and equipment for them – class IIa,
see enclosure**

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **MED000144-02/01 of: 17.05.2021,**

MED000144-03/01 of: 17.05.2021, MED000144-09/01 of: 04.05.2021.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design-Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).


Edition 1

The first issue of this Certificate from 19.05.2021 with validity until 26.05.2024

The validity of this Certificate is limited until: **26.05.2024**

19.05.2021

Prague


Mgr. Miroslav Sedláček
Head of Certification Body



Stamp



* C E R / M E D 2 1 0 0 1 2 *

MED000144-02

Infusion, transfusion, dialysis and urodynamic sets and equipment for them – class IIa

GAMAPLUS

GAMAPLUS 1,8 x 450 LL
GAMAPLUS 1,8 x 450 LLK
GAMAPLUS 1,8 x 1500 LL
GAMAPLUS 1,8 x 1800 LL
GAMAPLUS 1,8 x 1800 LLK
GAMAPLUS 1,8 x 450 UNIV
GAMAPLUS 1,8 x 1800 UNIV
GAMAPLUS 3,0 x 150 LL
GAMAPLUS 3,0 x 300 LL
GAMAPLUS POCARD
GAMAPLUS 3,0 x 2500 LL
GAMAPLUS 3,0 x 3500 LL
GAMAPLUS 3,0 x 450 MVT
GAMAPLUS 3,0 x 150 YLL
GAMAPLUS 3,0 x 150 LCH
GAMAPLUS 4,5 x 20 LCH
150 cm, extension PVC tube
150 cm, extension PVC tube for light-sensitive drugs
200 cm, extension PVC tube for light-sensitive drugs
50 cm, extension PVC tube for light-sensitive drugs
Connecting Tubing 2-way
Connecting Tubing 4-way
Connection tubing with needleless port

Infusion sets for overpressure infusion

Infusion set IS-121
Infusion set IS-123
Infusion set IS-126 – 62 ShA
Infusion set IS-126 180 cm – 62 ShA
Infusion set IS-126T – 62 ShA
Infusion set IS-127 P
Infusion set IS- 127 P 180 cm
Irrigation set
Irrigation - cooling set

Transfusion sets

Transfusion set TS-201
Transfusion set TS-203
Transfusion set TS-204



Transfusion sets for blood bags

Transfusion set for blood bags TSV-221
Transfusion set for blood bags TSV-222

Dialysis sets

Dialysis set DIS 06-16 UNIV

Flow Reversal Device

HDF on-line set

Urodynamic sets

Small urodynamic set USM
Small urodynamic set USM – 1845 mm
Small urodynamic set USM - S

Needleless port

Needleless port
Needleless port - red

Stopcocks

Ramp 3-taps NO PVC
Ramp 5-taps NO PVC
Ramp 3-way with NP NO PVC
Ramp 5-way with NP NO PVC
Three-way tap – red/blue/white NO PVC

Safety valve

Safety valve NO PVC

End of list

