ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

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

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

EC CERTIFICATE PRODUCTION QUALITY ASSURANCE

issued in accordance with Annex 5 of Government Order No. 54/2015 Coll. (Annex V of Directive 93/42/EEC)

No.: MED 210005

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried audit results has decided that the quality system limited to the manufacturing aspects relevant to securing and maintaining sterile conditions established at the

manufacturer	**GAMA GROUP a.s.** **Mánesova 11/3b, 370 01 České Budějovice, Czech Republic**
in manufacturing sites	**GAMA GROUP a.s. závod Jimramov** **Ubušínská 20, 592 42 Jimramov, Czech Republic**
for medical device(s)	**Infusion sets for gravity feed, transfer sets and equipment for dialysis – class I sterile, see Enclosure**

meets the provisions of Annex 5 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex V 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. MED000145-02/01 of: 17.03.2021, MED000145-03/01 of: 17.03.2021, MED000145-06/01 of: 17.03.2021.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 5 clause 4 of Government Order No. 54/2015 Coll. (Annex V clause 4 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.

Edition 1

The first issue of this Certificate from 31.03.2021 with validity until 26.05.2024
The validity of this Certificate is limited until: 26.05.2024

elektrotechnický zkušební ústav ezú -1- Pod lisem 129/2, 171 02 Praha 8 - Troja

19.05.2021

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

* C E R / M E D 2 1 0 0 0 5 *

Infusion sets for gravity feed, transfer sets and equipment for dialysis – class I sterile

Infusion sets for gravity feed
- Infusion set IS-101
- Infusion set IS-102
- Infusion set IS-103
- Infusion set IS-103 – pack. 4x50 pcs
- Infusion set IS-103/K
- Infusion set IS-103/K – pack. 4x50 pcs
- Flow regulator infusion

Transfer sets
- Transfer set (V606386-ND)
- Transfer set PS (V606386-02ND)
- Transfer set PS (V606386-03ND)

Priming sets of dyalysis sets

HD sampling set

Double-ended piercing spike

Separation filter

End of list

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