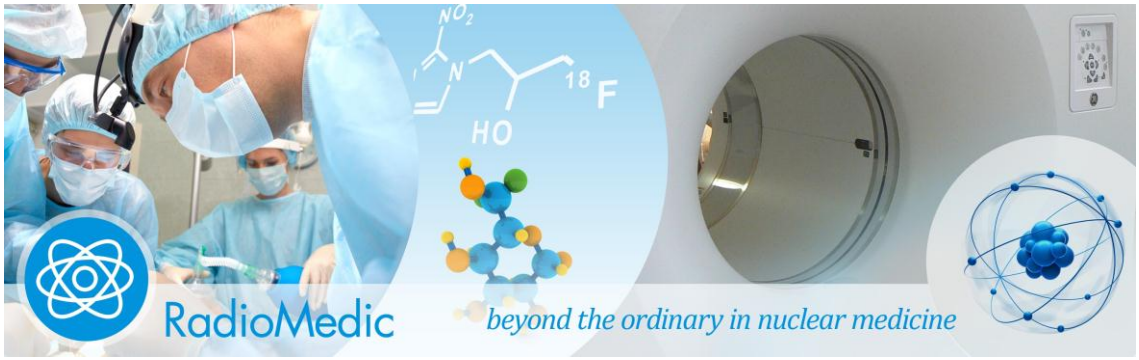

www: www.radiomedic.cz **e-mail:** info@radiomedic.cz x odbyt@radiomedic.cz

Company RadioMedic Ltd. deals with the development, manufacturing and distribution of radiopharmaceutical preparations.

The company is a holder of the **GMP** certificate for manufacturing of human pharmaceuticals and human pharmaceuticals in a clinical study in the phase I, II and III (see attachment No.1).

Newly RadioMedic is also the holder of authorization to DISTRIBUTE medical products and substances in the Czech Republic (see attachment No.2).

For **both activities** our company holds ČSN EN ISO 9001:2009 certification (see attachment No.3).

RadioMedic Ltd. has a contractual manufacturing site in the Slovak Republic – BIONT a.s., Karloveská 63, P.c. 841 04 Bratislava, where the company manufactures one of the radiopharmaceuticals with the Slovak marketing authorization.
The company holds 5 radiopharmaceuticals with a marketing authorization in the Czech Republic and 2 radiopharmaceuticals with a marketing authorization in the Slovak Republic.

The company manufactures **radiodiagnostics** for **positron emission tomography** (PET) marked with positron isotope ^{18}F, **generators producing** ^{81m}**Kr** for lung diagnostics and **natrium iodide** containing ^{123}**I** for thyroid diagnostics by means of the **single photon emission computed tomography** (SPECT).

RadioMedic Ltd. has **extensive experience** with **implementing of the manufacturing process of radiopharmaceuticals in the GMP mode, elaborating the GMP documentation and providing all the method validation** which is connected with the implementation of the devices for the manufacturing technology, manufacturing process, quality control and quality assurance. RadioMedic Ltd. is able to ensure the entire **staff training for a new manufacturing site** at the current company's production site as well as at a new manufacturing site at the customer's. The company implements all the necessary technology in a quality meeting the customer´s requirements (radiochemicals or radiopharmaceuticals).

In the field of research, the company offers cooperation and consultancy for the selected preparation with a good potential of being applied on the pharmaceutical market - realization process of the preclinical study, clinical study and the final marketing authorization. The company has its own rich knowledge and experience with realization of preclinical studies as well as clinical studies in the Czech Republic and the Slovak Republic.

Another area of interest is connected with **proposal, construction and recycling of the target systems** for the radiochemical production in the cyclotrone, **sales of manufacturing synthesizing technology** and **quality control service.**

Manufacturing of Radiopharmaceuticals and Radiopharmaceutical Precursors with a Marketing Authorization

[^{18}F]-PET Radiopharmaceuticals with a Marketing Authorization in the Czech Republic or in the Slovak Republic

- marked with the most common PET radionuclide ^{18}F with a half-life of **109,8 min** and maximum positron energy **633 keV**
- carrier-free, sterile and non-pyrogenic radiodiagnostics
- intravenous application

2-[^{18}F]-FDG (2-deoxy-2-[^{18}F]fluoro-D-glucose for injection)

- the most common PET radiopharmaceutical for imaging of deposits in the tissues with an intensive glukose metabolism
- used in imaging of an increased comsuption of glucose in the brain, heart and tumorous deposits in tissues (diagnosis, staging and monitoring of the used therapy of tumor diseases)
- the company has released and delivered 5 100 lots of *2-[^{18}F]-FDG* with reliability of delivery of 99,6 % in the year 2010

[^{18}F]NaF, INJ ([^{18}F]Natrium fluoride, injection)

- the preparation intended for topographical analysis of regional alterations in the skeleton and for in vivo determination of the entire metabolic flow in the skeleton (primary and secondary malignant tumors of the skeleton and joint diseases)

3´-[^{18}F]FLT, INJ (3´-deoxy-3´-[^{18}F]fluorothymidin, injection)

- the preparation intended for diagnostics of the quickly proliferative tumors, especially in brain and lungs

SPECT Radiopharmaceuticals with a Marketing Authorization in the Czech Republic or in the Slovak Republic

Radionuclide Generator ^{81}Rb /^{81m}Kr

- half-life of the **^{81m}Kr** is **13,1 s**, gamma emission energy is **190,4 keV**
- a radiopharmaceutical for the investigation of the ventilation of the lungs (pulmonary embolism, chronic obstruction disease, chronic bronchitis, asthma and bronchogenic carcinoma)
- reliable imaging of the real state of the ventilation of the lungs thanks to elimination of the false-negative results (the passive ventilation of the lungs)
- low irradiation exposure of the patient and the absence of radioactive waste
- difference of the emitted gamma quantum of ^{81m}Kr (190,4 keV) and ^{99m}Tc (140,5 keV) enables a parallel investigation of the ventilation of the lungs and pulmonary embolism
- the company has released and delivered 1 250 lots of radionuclide generators $^{81}Rb/^{81m}Kr$ with reliability of delivery of 99,6 % in the year 2010

Jodid 123 (^{123}I -Natrium Iodide)

- the active substance is natrium iodide
- a radiopharmaceutical for the thyroidal examination and detection of potential metastases of the thyroid carcinoma after thyroid ablation.

- the preparation is eliminated with the half-life of the renal clearance 8 h
- the radiopharmaceutical performs a high specificity for imaging of the thyroid gland, thyroid carcinoma and thyroid metastases
- the substance performs very low irradiation exposure of the patient (the effective dose is 0,23 mSv/MBq with 55 % accumulation in the thyroid gland)

Radiofarmaceutics Precursors

^{124}I – precursor – specification:

RADIONUCLIDE	^{124}I
HALF-LIFE	4,176 d
FORM	solution 0.01M NaOH (sodium hydroxide)
RADIONUCLIDE PURITY	> 99.5 %
RADIOCHEMICAL PURITY	> 95 % I^-
VOLUME ACTIVITY	> 100 MBq/ml
CALIBRATION	12.00 on the day of delivery
EXSPIRATION	4 d
STORAGE CONDITIONS	15–25 °C

^{177}Lu – precursor – specification:

RADIONUCLIDE	^{177}Lu
HALF-LIFE	6,71 d
FORM	solution ^{177}Lu in 0,05M HCl
RADIONUCLIDE PURITY	>99 %
RADIOCHEMICAL PURITY	> 95 %
SPECIFIC ACTIVITY	20 GBq/mg at the time of production
CALIBRATION	12.00 on the day of delivery
EXSPIRATION	7 d
STORAGE CONDITIONS	15–25 °C

^{166}Ho – precursor – specification:

RADIONUCLIDE	^{166} Ho
HALF-LIFE	26,83 h
FORM	solution ^{166}Ho in 0,05M HCl
RADIONUCLIDE PURITY	>99 %
RADIOCHEMICAL PURITY	> 95 %
SPECIFIC ACTIVITY	1,5 GBq/mg at the time of production
CALIBRATION	12.00 on the day of delivery
EXSPIRATION	30 h
STORAGE CONDITIONS	15–25 °C

^{68}Ga – precursor (solution with acetone for labelling) – specification:

RADIONUCLIDE	^{68}Ga
HALF-LIFE	67,629 min
FORM	[^{68}Ga]$GaCl_3$ in HCl + aceton
RADIONUCLIDE PURITY	>99 %
RADIOCHEMICAL PURITY	> 95 %
VOLUME ACTIVITY	depending on the generator power

CALIBRATION	12.00 on the day of delivery
EXSPIRATION	70 min
STORAGE CONDITIONS	15–25 °C

An alternative technology to ^{68}Ga precursor manufacturing – available technology for manufacturing of the solution without acetone (pharmaceutical quality).

^{99m}Technecistan – precursor manufactured using the extraction method from ^{99}Mo - specification:

RADIONUCLIDE	^{99m}Tc
HALF-LIFE	6,02h
FORM	Technetium solution [^{99m}Tc] in 0,9% NaCl
APPEARANCE	transparent, colour-less solution, particle free
pH	4-8
RADIONUCLIDE PURITY	> 95 %
RADIOCHEMICAL PURITY	molybden-99 volume max. 0,1% content of other radionuclide impurities max. 0,01%
CHEMICAL PURITY	aluminium ≤ 5mg/ml 2-butanon (MEK) ≤ 3000 mg/l *)
BACTERIAL ENDOTOXINS	≤ 17,5EU/ml *)
STERILITY	sterile
CALIBRATION	12.00 on the day of delivery
EXSPIRATION	12 hod from the end of production
STORAGE CONDITIONS	do 25 °C, protected from frost

*) valid for a maximum recommended applicable volume (10 ml)

^{86}Y – precursor

Target in the final phase of the testing, the manufacturing technology is fully functional.

Manufacturing Device for Preparation of Solutions of the Radiopharmaceutical Precursors

The device is used for preparation of solutions of isotopes prepared in the reactor by the means of irradiation of the matrix in a titanium ampule.

The device consists of the following parts:

- holder of the titanium ampule with an opening device and a vertical pneumatic needle carrier.
- washing-out part consisting of the tap actuators and the holder of the single-use material. (taps, vials with washing-out solutions and connecting material).
- evaporatione part created by the heating block with regulation, tap actuators and single-use material.
- operating unit integrated in the switch board placed out of the hot cell.
- a laptop equipped with the graphic interface Reliance for creating of the programmes and for data entering and editing of the variable technologic parametres.

Size:

- holder of the titanium ampule with the needle carrier: 250 x 200 x 610 mm
- washing-out part with the tap actuators: 150 x 270 x 190 mm
- holder of the single-use material: 320 x 300 x 350 mm

Offer of the Target Technology

^{81}Rb/^{81m}Kr - target system KrIII

^{124}I – service recycling of the used targets possible

Offer of the Manufacture Technology

^{18}F-FLT – module TRACERLab Mx FDG, HPLC with additional accessories.

^{18}F-NaF - module TRACERLab Mx FDG.

^{18}F-FMISO - module TRACERLab Mx FDG.

^{18}F-FET - module TRACERLab FX-FN.

^{123}I-MIBG – the manufacturing process is currently being automatized.

Research and Development

[^{18}F]-PET Radiopharmaceuticals

^{18}F-pharmaceuticals (half-life is 109,8 min., maximum positron energy is 0,633 MeV) which occur in development progress are following:

[^{18}F]FMISO, INJ SOL ([^{18}F]fluormisonidazole, injection solution)

- the radiopharmaceutical with the active substance which selectively binds to the hypoxic cells (tumor cells are more sensitive to the radiotherapy and chemotherapy in presence of oxygen in tissue and consequently the number of the hypoxic cells is a limitation factor for the therapy effect)
- pre-clinical studies have been performed, preparations are being made to apply for clinical assessment

[^{18}F]TOCA, INJ SOL ([^{18}F]FP-Gluc-Lys^{0}-Tyr^{3}-octreotate, injection solution)

- the detection substance on the basis of the octreotide analogue intended for gastroenteropancreatic neuroendocrinological (GEP) tumors in the presence of the somatostatine receptors
- the first active intermediate is being synthetized
- the completion of the preparation of the active substance expected this year

[^{18}F]FET, INJ SOL (O-(2-[^{18}F]fluorethyl)-L-tyrosine, injection solution)

- a preparation for diagnosis of the neuronal and brain tumors
- the tumor/normal tissue ratio is much higher in comparison with 2-[^{18}F]-FDG
- highly selective to the tumor cells, does not accumulate in the inflammatory and necrotic tissues
- pre-clinical studies have been performed, preparations are being made to apply for clinical assessment

Radiopharmaceutical Precursors with Beta Radionuclides *^{177}Lu* and *^{166}Ho*

- the half-life of the **^{177}Lu** is 6,67 d and maximum beta energy 497 keV
- the half-life of the ^{166}**Ho** is 26,7 h and maximum beta energy 1,8 MeV

- the precursors are used in the palliative treatment of bone metastases and radiosynoviorthesis
- complexation properties of the radionuclides were verified on chelates (DOTA and DTPA - the complexation ratio was higher than 95 % in the pH range 5-9)

Unconventional PET Radionuclides

^{18}F half-life is quite short for many types of in vivo use (metabolism of the monoclonal antibodies and their fragments or biodistribution of the radiopharmaceuticals etc.)
The attention is focused on other positron radionuclides with longer half-life:

- **^{86}Y** (the half-life is 14,7 h)
- **^{124}I** (the half-life is 4,18 d)
- **^{68}Ge / ^{68}Ga generator** (the half-life of the ^{68}Ge is 270,8 d and ^{68}Ga is 67,6 min)

The application of the positron emitters enables PET determination of the biodistribution and metabolism of the radiotherapeutics marked by the **^{90}Y and** the **^{131}I**.

SPECT Radiopharmaceuticals

The radiopharmaceutical preparations are marked by the isotope **^{123}I** (the half-life is 13,27 h, gamma emmision quantum is 159 keV).

Jobenguan 123, injection solution (^{123}I-Iobenguan, ^{123}I-MIBG)

- the active substance is metaiodobenzylguanidine in jobenguan which is an analogue of the adrenergic blocator
- metaiodobenzylguanidine manifests an affinity to the adrenergic receptor tissue and it is concentrated in the chromaffin cells of the adrenal gland, myocard and other tissues rich in sympathetic part of the vegetative nervous system
- the substance is an appliance essential for imaging of the feocytochromes, neuroblastoma, for tumor detection of the adrenal medulla and of such tumors metastases
- the preparation is also a useful tool for diagnostics in cardiology
- performing a high specificity to the imaged tissues and very low irradiation exposure of the patient

Hippuran 123, injection solution (^{123}I-Hippuran)

- the active substance is sodium salt of the orthoiodohippuric acid
- it is eliminated by renal clearance after intravenous injection (80 % through proximal tubular secretion, the rest through glomerular filtration)
- the time of the renal throughput is about 4 minutes in healthy patients (the diagnostics of the renal function)
- the substance has a high sensitivity to the imaging process and very low irradiation exposure of the patient (0,027 mSv/MBq)

Attachment No.1

SÚKL
Státní ústav pro kontrolu léčiv
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tel.: +420 272 185 111
fax: +420 271 732 377
e-mail: posta@sukl.cz
web: www.sukl.cz

certifikát sp.zn./ certificate Ref.No: sukls88922/2011

CERTIFIKÁT SVP PRO VÝROBCE
Část 1

Vydaný po inspekci v souladu s článkem 111(5) Směrnice 2001/83/EC ve znění pozdějších přepisů a s §13, odst. 2, písm. a bod 3 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů

Příslušný orgán České republiky potvrzuje následující:

Výrobce:
RadioMedic s.r.o.
Husinec-Řež 289
250 68 Řež

Adresa místa výroby:
RadioMedic s.r.o.
Husinec-Řež 289
250 68 Řež

Byl inspektován v souladu s plánem inspekcí v souvislosti s povolením k výrobě sp.zn. sukls96844/2008, poslední změna sp.zn. sukls33674/2011 ze dne 03.03.2011, v souladu s článkem 40 Směrnice 2001/83/EC
převedeným do národní legislativy jako:
§ 62 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů.

Na základě znalostí získaných během poslední inspekce, která byla provedena dne 10.12.2010, je tento výrobce považován za subjekt splňující
požadavky a návody správné výrobní praxe stanovené směrnicí 2003/94/EC[1].

[1] Tyto požadavky splňují doporučení SZO na SVP.

Tento certifikát odráží stav výrobního místa v čase výše zmíněné inspekce a nemělo by se spoléhat na to, že bude odrážet stav shody po uplynutí více než tří let od data inspekce. Po této době by měl být konzultován vydávající orgán. Pravost tohoto certifikátu může být ověřena u vydávajícího orgánu.

Certifikát SVP sp.zn.: sukls88922/2011
Datum: 10.05.2011
Strana 1 z 2
Jméno: František Chuchma
e-mail: posta@sukl.cz
Podpis:
F-INS-002-21/09.09.2009

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended and Section 13, paragraph 2, letter a, point 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended.

The competent authority of the Czech Republic confirms the following:

The manufacturer:
RadioMedic s.r.o.
Husinec-Řež 289
250 68 Řež

Site address:
RadioMedic s.r.o.
Husinec-Řež 289
250 68 Řež

Has been inspected under the national inspection programme in connection with manufacturing authorisation no sukls96844/2008, last variation no sukls33674/2011 issued on 03/03/2011 in accordance with Art. 40 of Directive 2001/83/EC
transposed in the following national legislation:
Section 62 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/12/2010, it is considered that it complies with
The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1].

[1] These requirements fulfil the GMP recommendation of WHO.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more then three years have elapsed since the date of inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

GMP Certificate Ref.No.: sukls88922/2011
Date: 10.05.2011
Page 1 / 2
Name
Phone number: +420 272 185 832
Signature of the authorised person of the competent authority

Část 2
☒ **Humánní léčivé přípravky**

1 VÝROBNÍ OPERACE
1.1 Sterilní přípravky

1.1.1 Asepticky připravované
1.1.1.4 Maloobjemové tekuté lékové formy (o objemu do 100 ml) (radiofarmaka)

1.1.2 Terminálně sterilizované
1.1.2.3 Maloobjemové tekuté lékové formy (o objemu do 100 ml) (radiofarmaka)

1.2 Nesterilní přípravky

1.2.1 Nesterilní přípravky
1.2.1.6 Tekuté pro vnitřní užití (radiofarmaka)

1.2.1.10 Radionuklidové generátory (pro inhalaci)

1.6 Kontrola jakosti
1.6.3 Chemické/Fyzikální
1.6.4 Biologické

Jakékoli omezení nebo vysvětlení vztahující se k rozsahu certifikátu:
Tento certifikát byl vydán v souvislosti se zánikem certifikátu sp.zn. sukls187613/2010, vydaného dne 10.02.2011 společnosti RadioMedic s.r.o., 250 68 Husinec – Řež 289. Ke dni 03.03.2011 došlo ke změně sídla a místa výroby na Husinec-Řež 289, 250 68 Řež.

Datum: 10.05.2011

podpis oprávněné osoby příslušného orgánu České republiky

František Chuchma
vedoucí inspekčního odboru

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
Česká republika
e-mail: posta@sukl.cz
telefon: +420 272 185 832
fax: +420 271 732 377

Part 2
☒ **Human Medicinal Products**

1 MANUFACTURING OPERATIONS
1.1 Sterile Products

1.1.1 Aseptically prepared
1.1.1.4 Small volume liquids (radiopharmaceuticals)

1.1.2 Terminally sterilised
1.1.2.3 Small volume liquids (radiopharmaceuticals)

1.2 Non-sterile products

1.2.1 Non-sterile products
1.2.1.6 Liquids for internal use (radiopharmaceuticals)
1.2.1.10 Radionuclide generators (for inhalation)

1.6 Quality control testing
1.6.3 Chemical/Physical
1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:
This certificate has been issued in connection with extinction of certificate ref. no. sukls187613/2010 issued on 10/02/2011 to the company RadioMedic s.r.o., 250 68 Husinec-Řež 289. With effect from 03/03/2011 the registered office adress and the manufacturing site adress was changed to Husinec-Řež 289, 250 68 Řež.

Date: 10.05.2011

signature of the authorised person of the competent authority of the Czech Republic

František Chuchma
Head of the Inspection section

State Institute for Drug Control
Šrobárova 48
100 41 Prague 10
Czech Republic
e-mail: posta@sukl.cz
phone: +420 272 185 832
fax: +420 271 732 377

Otisk úředního razítka

Certifikát SVP sp.zn.: sukls88922/2011
Strana 2 z 2
Jméno: František Chuchma
e-mail: posta@sukl.cz
Podpis:
F-INS-002-21/09.09.2009

GMP Certificate Ref.No.: sukls88922/2011
Page 2 / 2
Name
Phone number: +420 272 185 832
Signature of the authorised person of the competent authority

SÚKL
Státní ústav pro kontrolu léčiv

Státní ústav pro kontrolu léčiv
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e-mail: posta@sukl.cz
web: www.sukl.cz

certifikát sp.zn./ certificate Ref.No:sukls91581/2011

CERTIFIKÁT SVP PRO VÝROBCE
Část 1

Vydaný po inspekci v souladu s článkem15 Směrnice 2001/20/EC a s §13, odst. 2, písm. a bod 3 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů

Příslušný orgán České republiky potvrzuje následující:

Výrobce:
RadioMedic s.r.o., Husinec-Řež 289, 250 68 Řež

Adresa místa výroby:
Husinec-Řež 289, 250 68 Řež

Byl inspektován v souladu s plánem inspekcí v souvislosti s povolením k výrobě sp.zn. sukls96844/2008, poslední změna sp.zn. sukls33674/2011 ze dne 03/03/2011, v souladu s článkem 13 Směrnice 2001/20/EC převedeným do národní legislativy jako: § 57 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů.

Na základě znalostí získaných během poslední inspekce, která byla provedena dne 19/10/2011, je tento výrobce považován za subjekt splňující požadavky a návody správné výrobní praxe stanovené směrnicí 2003/94/EC[1].

[1] Tyto požadavky splňují doporučení SZO na SVP.

Tento certifikát odráží stav výrobního místa v čase výše zmíněné inspekce a nemělo by se spoléhat na to, že bude odrážet stav shody po uplynutí více než tří let od data inspekce. Po této době by měl být konzultován vydávající orgán.

Pravost tohoto certifikátu může být ověřena u vydávajícího orgánu.

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER
Part 1

Issued following an inspection in accordance with Art. 15 of Directive 2001/20/EC and Section 13, paragraph 2, letter a, point 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended.

The competent authority of the Czech Republic confirms the following:

The manufacturer:
RadioMedic s.r.o., Husinec-Řež 289, 250 68 Řež

Site address:
Husinec-Řež 289, 250 68 Řež

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. sukls96844/2008, last variation no.sukls33674/2011 issued on 03/03/2011 in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation: Section 57 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 19/10/2011, it is considered that it complies withThe principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC[1].

[1] These requirements fulfil the GMP recommendation of WHO.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more then three years have elapsed since the date of inspection, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

Certifikát SVP sp.zn.: sukls91581/2011
Datum:16/12/2011
Strana 1 z 2
Jméno: František Chuchma
e-mail: posta@sukl.cz
Podpis:
F-INS-002-21/09.09.2009

GMP Certificate Ref.No.: sukls91581/2011
Date:16/12/2011
Page 1 / 2
Name
Phone number: +420 272 185 832
Signature of the authorised person of the competent authority

Část 2

☒ **Humánní hodnocené léčivé přípravky pro fázi I, II a III klinického zkoušení**

1 VÝROBNÍ OPERACE
1.1 Sterilní přípravky

1.1.1 Aseptický připravované

1.1.1.4 Maloobjemové tekuté lékové formy (o objemu do 100 ml - radiofarmaka)

1.1.2 Terminálně sterilizované

1.1.2.3 Maloobjemové tekuté lékové formy (o objemu do 100 ml - radiofarmaka)

1.2 Nesterilní přípravky

1.2.1 Nesterilní přípravky

1.2.1.6 Tekuté pro vnitřní užití (radiofarmaka)

1.6 Kontrola jakosti
1.6.3 Chemické/Fyzikální
1.6.4 Biologické

Jakékoli omezení nebo vysvětlení vztahující se k rozsahu certifikátu:

Datum:16/12/2011

podpis oprávněné osoby příslušného orgánu České republiky

František Chuchma
vedoucí inspekčního odboru

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e-mail: posta@sukl.cz
telefon: +420 272 185 832
fax: +420 271 732 377

Otisk úředního razítka

Certifikát SVP sp.zn.: sukls91581/2011
Strana 2 z 2
Jméno: František Chuchma
e-mail: posta@sukl.cz
Podpis:
F-INS-002-21/09.09.2009

Part 2

☒ **Human Investigational Medicinal Products for phase I, II, III clinical trials**

1 MANUFACTURING OPERATIONS
1.1 Sterile Products

1.1.1 Aseptically prepared

1.1.1.4 Small volume liquids (radiopharmaceuticals)

1.1.2 Terminally sterilised

1.1.2.3 Small volume liquids (radiopharmaceuticals)

1.2 Non-sterile products

1.2.1 Non-sterile products

1.2.1.6 Liquids for internal use (radiopharmaceuticals)

1.6 Quality control testing
1.6.3 Chemical/Physical
1.6.4 Biological

Any restrictions or clarifying remarks related to the scope of this certificate:

Date:16/12/2011

signature of the authorised person of the competent authority of the Czech Republic

František Chuchma
Head of the Inspection section

State Institute for Drug Control
Šrobárova 48
100 41 Prague 10
Czech Republic
e-mail: posta@sukl.cz
phone: +420 272 185 832
fax: +420 271 732 377

GMP Certificate Ref.No.: sukls91581/2011
Page 2 / 2
Name
Phone number: +420 272 185 832
Signature of the authorised person of the competent authority

Attachment No.2

STÁTNÍ ÚSTAV PRO KONTROLU LÉČIV
State Institute for Drug Control

Šrobárova 48, 100 41 PRAHA 10
tel.: +420 272 185 111, fax: +420 271 732 377, e-mail: posta@sukl.cz

Sp.zn. sukls153012/2011 V Brno Dne 2011-08-15
Ref.No. In Date

CERTIFIKÁT
SPRÁVNÉ DISTRIBUČNÍ PRAXE

CERTIFICATE OF GOOD DISTRIBUTION PRACTICE

Státní ústav pro kontrolu léčiv se sídlem v Praze 10, Šrobárova 48, jako orgán příslušný k vydávání certifikátu správné distribuční praxe podle § 13 odst. 2 písm. a) bod 3 zákona č. 378/2007 Sb., o léčivech a o změnách některých souvisejících zákonů (zákon o léčivech), ve znění pozdějších předpisů, osvědčuje, že společnost:

State Institute for Drug Control, seated in Prague 10, Šrobárova 48, as the appropriate authority for certification according to Section 13, paragraph 2, letter a), point 3 of the Act No. 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts ("Act on Pharmaceuticals"), as amended, certifies that the company:

RadioMedic s.r.o., Husinec-Řež 289, 250 68 Řež

je držitelem povolení k distribuci léčivých přípravků podle zákona č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů, vydaného pod sp.zn. sukls22833/2011 dne 11.4.2011, platného pro následující prostory:

RadioMedic s.r.o., Husinec-Řež 289, 250 68 Řež (1 místnost v suterénu budovy č. 221 o ploše 14 m^2).

is a holder of authorisation for distribution of medicinal products according to the Act No. 378/2007 Coll., Act on Pharmaceuticals, as amended, under the reference number sukls22833/2011from 11.4.2011, covering the following site:

RadioMedic s.r.o., Husinec-Řež 289, 250 68 Řež (1 room in building No. 221 – area 14 m^2).

pro následující rozsah distribuce: **distribuce léčivých přípravků**

for the following type of distribution: **wholesale distribution of medicinal products**

Výše uvedený distributor splňuje požadavky správné distribuční praxe podle zákona č. 378/2007 Sb., o léčivech, ve znění pozdějších předpisů, a vyhlášky č. 229/2008 Sb., o výrobě a distribuci léčiv. Inspektoři Státního ústavu pro kontrolu léčiv provádí ve výše uvedené společnosti v pravidelných intervalech kontroly. Poslední kontrola byla provedena dne 23.3.2011.

Above mentioned distributor conforms with requirements of Good Distribution Practice according to the Act No. 378/2007 Coll., Act on Pharmaceuticals, as amended, and Decree No. 229/2008 Coll., on the Manufacture and Distribution of Pharmaceuticals. Inspectors of the State Institute for Drug Control carry out inspections of the above mentioned company in regular intervals. Last inspection was peformed on 23.3.2011.

Státní ústav pro kontrolu léčiv v Praze -13-

PharmDr. Ivan Buzek
Vedoucí odboru lékárenství a distribuce
Head of the Pharmacy and Distribution department

F-LEK-009-16/15.10.2008

SÚKL

Attachment No.3

BUREAU VERITAS
Certification

Certification

Awarded to

RadioMedic s.r.o.

Husinec-Řež 289, 250 68 Řež
Czech Republic

Bureau Veritas certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standard detailed below:

Standard

ČSN EN ISO 9001:2009

Scope of supply

MANUFACTURING AND DISTRIBUTION OF MEDICINAL PRODUCTS, RESEARCH AND DEVELOPMENT IN THE FIELD OF NATURAL SCIENCE, TECHNOLOGY AND SOCIAL SCIENCE.

Original Approval Date: 11th APRIL 2011

Subject to the continued satisfactory operation of the organisation's Management System, this certificate is valid until: 10th APRIL 2014

To check this certificate validity please call: +420 210 088 215

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.

Date: 11th APRIL 2011

Certificate Number: 11000173

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

S 3100

MANAGING OFFICE: BUREAU VERITAS CZECH REPUBLIC, spol. s r.o., Olbrachtova 1, 140 02 Praha 4, Czech Republic

ISSUING OFFICE ADDRESS: BUREAU VERITAS CZECH REPUBLIC, spol. s r.o., Olbrachtova 1, 140 02 Praha 4, Czech Republic