DECLARATION OF CONFORMITY WITH EUROPEAN STANDARDS

issued according to EN 45014

VARI TEC s.r.o.

V. Opatrného 300 517 21 Týniště nad Orlicí ,CZ IČO: 60915889,DIČ: CZ60915889 We producers: LYNAX s.r.o.

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are declaring herewith on our own responsibility that the products for manipulation with radiopharmaceuticals emitting γ radiation, e.g. ^{99m}Tc

PT442

In all manufactured versions

The device type numbers

meet the requirements of following technical standards and documentation of the producer

- CZ Law Nr. 102/2001 Sb., general safety
- European Standards EN 45014, EN ISO 2768-1 and -2, EN ISO 4753, EN 20273, EN ISO 6947, EN 25817, EN 1011-3, ISO 261 a 262, EN 20286-1 a -2, EN ISO 4287
- Sets of documentation of applicable device type number.
- The devices mentioned in the declaration list are are safe when used in accordance with the instruction manual. We producer have taken all measures to ensure the conformity of all products we place on the market with the documents mentioned above.

Intention of products: Devices provide safe and simple method of manipulation with radiopharmaceuticals. Their purpose is to reduce the risk of exposure and contamination of emploees handling radioactive solutions. They facilitate maintaining aseptic conditions when manipulating with radiopharmaceuticals.

Issued in:

Prague

Date:

9.3.2015

Issued by: JiříKrálík

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