CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

The document, decision No. UR/RR/1122/13 of 09.07.2013 made by the President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products concerning PoltechMIBI kit manufactured by the National Nuclear Research Center in Otwock, has been drawn up on three numbered pages of a light blue form, with a red official seal with Poland's emblem at the bottom. ---

/ --- / A crowned eagle, Poland's emblem ---

PRESIDENT ---
of The Office for Registration of Medicinal Products, ---
Medical Devices, and Biocidal Products ---

Warsaw, 09.07.2013 ---

Ref. No. **UR/RR/1122/13** ---

To: **National Center for Nuclear Research -**
ul. Andrzeja Sołtana 7 ---
05-400 Otwock ---

DECISION ---

In compliance with Art. 7 par. 2 and Art. 29 par. 2 of the act of 6th September 2001 Pharmaceutical Law (Journal of Laws of 2008, No. 45, item 271 as amended) ---

the period of validity of Marketing Authorisation No. R/3269 granted for the PoltechMIBI medicinal product has been extended for an indefinite time ---

Name:	PoltechMIBI ---
Commonly used name:	Technetii (^{99m}Tc) sestamibi solutio iniectabilis
Pharmaceutical form, strength and active substance dose:	Kit for production of a radiopharmaceutical preparation, 1 mg p[$(MIBI)_4Cu$][BF_4] ---
Administration route:	Intravenous ---
Person responsible:	The National Center for Nuclear Research --- ul. Andrzeja Sołtana 7 --- 05-400 Otwock ---
Name and address of manufacturer wherein the batch is released:	The National Center for Nuclear Research --- ul. Andrzeja Sołtana 7 --- 05-400 Otwock ---

Digitally signed by Bolea Petru
Date: 2023.07.11 09:50:14 EEST
Reason: MoldSign Signature
Location: Moldova

PRZYSIĘGŁY TŁUMACZ JĘZYKA ANGIELSKIEGO KRYSTYNA SACHMACIŃSKA NR TP/1920/06

Name and address of manufacturer wherein the batch is controlled:	The National Center for Nuclear Research --- ul. Andrzeja Sołtana 7 --- 05-400 Otwock ---
Full qualitative composition:	[tetra (2-methoxy-2-methylopropyl-1-isonitrylo)] – copper (I) tetrafluoroborate --- Stannous chloride dihydrate --- L-cysteine hydrochloride monohydrate --- Sodium citrate dihydrate --- D-mannitol ---
Package size: 3 pieces: 6 pieces:	- Code: 5 9 0 9 9 9 0 3 2 6 9 1 4 - Code: 5 9 0 9 9 9 0 3 2 6 9 2 1
Packaging type:	A 10 ml glass vial closed with a rubber plug and aluminium caps in a cardboard box. ---
Storage and transportation requirements:	Store in a refrigerator (from 2°C to 8°C). --- During transportation (not longer than 7 days), temperature below 35°C is admissible. ---
Expiry period:	A kit – 1 year. --- After being dissolved and radiolabelled in a solution of sodium pertechnetate (^{99m}Tc), ^{99m}Tc-MIBI may be used for up to 12 hours if stored below 25°C. ---
Availability:	Medicinal product used exclusively in in-patient healthcare facilities – Lz. ---

REASONS FOR THIS DECISION ---

Pursuant to Art. 107 § 4 of the Code of Administrative Procedure, it is departed from giving reasons for this decision since the latter accepts the party's request in its entirety. ---

Instruction: ---

Pursuant to Art. 127 § 3 and Art. 129 § 2 of the act of 14th June 1960 Code of Administrative Procedure (i.e. Journal of Laws of 2013, item 267), the party is entitled to apply to the President of The Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products for re-examination of its case within 14 days of this decision being served thereto. ---

A red round seal with Poland's emblem, reading: ---
President of the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products *1* ---

A stamp, reading: ---
pp. President ---
VICEPRESIDENT ---
For Medicinal Products ---
/ --- / *Signature illegible* ---
Marcin Kołakowski, MPharm. ---

Copies to: ---

1. The Party's proxy: ---
   Dariusz Socha, National Center for Nuclear Research ---
   ul. Andrzeja Sołtana 7 ---
   05-400 Otwock ---
2. File copy ---

UR.DZL.ZRN.4030.0078.2012 ---

I, the undersigned, Krystyna Sachmacińska, sworn translator of the English language registered under No. TP/1920/06 on the List of Sworn Translators kept by the Minister of Justice of the Republic of Poland, certify that this is a true and correct translation of an original document compiled in the Polish language. This document comprises four pages of sworn translation.
Warsaw, 16th September 2013 *Repertory No. 239 / 2013.*