Bureau of Laboratory Quality Standards
Ministry of Public Health

This is to certify that

The Laboratory of

Bureau of Radiation and Medical Devices
Department of Medical Sciences

88/7 Moo 4, Tiwanon Road, Talad - Khwan,
Muang Nonthaburi, Nonthaburi 11000, Thailand

has been accepted as an
accredited laboratory complying with the ISO/IEC 17025:2017
and the requirement of the Bureau of Laboratory Quality Standards
The laboratory has been accredited for specific tests
listed in the scope within the field of

Medical Devices Testing

(Mr.Surasak Muenphon)
Director of Bureau of Laboratory Quality Standards

Date of Accreditation: 23 August 2024
Valid Until : 22 September 2026 **Accreditation Number** 4050/50

The laboratory of Bureau of Radiation and Medical Devices, Department of Medical Sciences has been accepted as an accredited laboratory in the field of radiation and medical devices testing for the following scopes.

No.	Type of Sample	Test	Method
1	Male condom - Natural rubber latex - Synthetic rubber latex	1. Quantity of lubricant	- ISO 4074:2015 - ISO 23409:2011 - TIS. 625-2559
		2. Length	
		3. Width	
		4. Thickness	
		5. Bursting pressure and volume	
		6. Freedom from holes, Visible defects and Individual containers with visibly open seals	
		7. Package integrity	
		8. Packaging and labeling	
2	Single-use medical examination gloves - Natural rubber latex - Synthetic rubber latex	9. Length	- TIS.1056, Vol. 1-2556 - ISO 11193-1:2020 - ASTM D 3578-19 - ASTM D 6319-19 - EN 455-1:2020+A1:2022 - EN 455-2:2024
		10. Width	
		11. Thickness	
		12. Water tightness	
		13. Force at break, Tensile strength, Elongation at break and Stress	
		14. Accelerated ageing	
3	Single-use sterile rubber surgical glove - Natural rubber latex - Synthetic rubber latex	15. Length	- TIS.538-2560 - ISO 10282:2023
		16. Width	
		17. Thickness	
		18. Water tightness	
		19. Force at break and Elongation at break	
		20. Accelerated ageing	

Accreditation Number 4050/50

Revision No. 02

Date of Accreditation : 23 September 2022

Date Revised 3 April 2025

Valid Until : 22 September 2026

Reviewed by Head of Laboratory Accreditation Section Saovanee Aromsook (Ms.Saovanee Aromsook)

The laboratory of Bureau of Radiation and Medical Devices, Department of Medical Sciences has been accepted as an accredited laboratory in the field of radiation and medical devices testing for the following scopes.

No.	Type of Sample	Test	Method
4	Sterile hypodermic syringes for single-use	21. Capacity	- TIS 777-2552 - ISO 7886-1:2017
		22. Scale	
		23. Barrel and finger grips	
		24. Piston and plunger	
		25. Nozzle	
		26. Lubricant	
		27. Generalization	
		28. Dead space	
		29. Piston leakage	
		30. Packaging	
		31. Symbol and labeling	
5	Sterile single-use syringes for insulin	32. Capacity	- TIS 2084-2552 - ISO 8537:2016
		33. Graduate scale	
		34. Barrel and finger grips	
		35. Piston and plunger	
		36. Nozzle	
		37. Needle	
		38. Generalization	
		39. Lubricant	
		40. Dead space	
		41. Piston leakage	
		42. Needle leakage	
		43. Packaging	
		44. Symbol and labeling	

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No.	Type of Sample	Test	Method
6	OSL card	45. Occupational exposure due to external sources of radiation	- IAEA Safety Standards Series No. GSG -7 Occupational Radiation Protection General Safety Guide 2018 - Radiation Dose Management for Fluoroscopically Guided Interventional Medical Procedures, NCRP Report No.168 - Whole Body Dose Algorithm for the Landauer In Light LDR Model 2 Dosimeter, Revision in Light N2003 - Whole Body Dose Algorithm for Landauer in Light Basic-OSLN Dosimeter (Validated by National Voluntary Laboratory Accreditation Program: NVLAP U.S.A.), 2008

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No.	Type of Sample	Test	Method
7	Magnetic Resonance Imaging (MRI)	46. Geometric accuracy 47. High-contrast spatial resolution 48. Slice thickness accuracy 49. Slice position accuracy 50. Image intensity uniformity 51. Ghosting ratio (Percent signal ghosting) 52. Low-contrast object detectability 53. Signal to noise ratio : SNR 54. Controlling access to the B_0 hazard area	Department of Medical Sciences. Quality Control Requirements of Magnetic Resonance Imaging (MRI), B.E: 2566
8	Co–60 teletherapy	55. Output measurement of Co–60 teletherapy	- International Atomic Energy Agency, IAEA TRS-398, 2024 - Quality Standard of Radiotherapy Machines, B.E. 2563
9	Linear accelerator	56. Output measurement of high-energy electron beam	
		57. Output measurement of high energy photon beam	
10	HDR After loading brachytherapy	58. Source strength	
11	X-ray therapy unit	59. Output measurement of X-ray therapy unit	

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No.	Type of Sample	Test	Method
12	Conventional radiography	60. Tube potential 61. Exposure time 62. Radiation output 63. Filtration 64. Beam – limiting device 65. Leakage radiation 66. Scatter radiation	Quality Standards of Diagnostic X-ray Machines, B.E. 2566
13	X–ray machine for animal	67. Tube potential 68. Exposure time 69. Radiation output 70. Filtration 71. Beam limiting device 72. Leakage radiation 73. Scatter radiation	
14	Mammogram	74. Tube potential 75. Exposure time 76. Radiation output 77. Filtration 78. Beam limiting device 79. High-contrast spatial resolution 80. Compression device 81. Automatic exposure control or AEC 82. Leakage radiation 83. Scatter radiation	

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No.	Type of Sample	Test	Method
15	Bone mineral densitometer X–ray machine	84. Phantom calibration 85. Radiation output 86. Scatter radiation	Quality Standards of Diagnostic X-ray Machines, B.E. 2566
16	Dental X–ray machine	87. Tube potential 88. Exposure time 89. Radiation output 90. Filtration 91. Beam limiting device 92. Leakage radiation 93. Scatter radiation	
17	Fluoroscopy X–ray machine	94. Tube potential 95. Fluoroscopic exposure switch 96. Filtration 97. Radiation output 98. Beam limiting device 99. Scatter radiation 100. Cumulative timing device 101. Last image hold 102. High-contrast resolution 103. Low-contrast resolution	

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No.	Type of Sample	Test	Method
18	Computed tomography X–ray machine	104. CT number accuracy 105. Image noise 106. High-contrast spatial resolution 107. Low-contrast resolution 108. Image uniformity 109. Image slice thickness 110. Image artefacts 111. Scan projection radiography accuracy 112. Table increment 113. Radiation dose 114. Medical X-ray room	Quality Standards of Diagnostic X-ray Machines, B.E. 2566
19	Mobile radiographic unit	115. Tube potential 116. Exposure time 117. Filtration 118. Radiation output 119. Beam limiting device 120. Leakage radiation 121. Scatter radiation	

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No.	Type of Sample	Test	Method
20	Industrial X–ray	122. Leakage radiation at 5 cm. from X-ray machine 123. Radiation warning symbol 124. Door interlock system 125. Distancing control for portable or mobile X–ray machine	Quality Standards of Diagnostic X-ray Machines, B.E. 2566
21	Non-invasive automated sphygmomanometers	126. Maximum permissible errors of the cuff pressure indication 127. Air leakage	- International Organization of Legal Metrology. OIML R149-1 : 2020(E) - International Organization of Legal Metrology. OIML R149-2 : 2020(E)
22	Non-invasive non-automated sphygmomanometers	128. Maximum permissible errors of the cuff pressure indication 129. Air leakage	- International Organization of Legal Metrology. OIML R148-1 : 2020(E) - International Organization of Legal Metrology. OIML R148-2 : 2020(E)

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