Receipt of Medical Device Manufacturing Specification Notification

Receipt of Specification Notification No. 66-1-2-2-0000204

This receipt of specification notification was given to:

Perceptra Company Limited

Medical Device Manufacturing Facility Registration No. GorThor. SorPhor. 26/2565

To show that the person reported medical device specifications pursuant to Section 19 of the Medical Devices Act, B.E. 2551 (A.D. 2008), and revisions for the medical instrument called

Inspectra CXR

Medical Device Specification See the Attachmen:

At the Medical Device Manufacturing Facility Named Perceptra Company Limited

Address No. 723 Supakarn Building

Lane/Alley - Road Charoen Nakhon Village No. -

Sub-district Khlong Ton Sai District Khlong San Province Bangkok Metropolis

Postal Code 10600 Tel. 082-0073411 Fax -

Product Owner’s Name and Location

Perceptra Company Limited, 723, Supakarn Building, Charoen Nakhon Road, Khlong Ton Sai Sub-district, Khlong San District, Bangkok Metropolis, Postal Code: 10600

This receipt of specification notification is valid until 31 December 2027

and may be used only for the facility specified in the receipt of specification notification.

Date of Issuance 13 Month March Year 2023

-QR Code- Food and Drug Administration

Ministry of Public Health Licensor

Certified Correct Translation

MPT

23 MAR 2023
Attachment

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Medical Device Specifications

Inspectra CXR is an AI-based software that analyzes adult frontal chest x-rays for signs of abnormalities in order to prioritize them for clinical review. Inspectra CXR identifies features suggestive of pleural effusion, tuberculosis, lung opacity, pulmonary edema, mass, nodule, cardiomegaly, and atelectasis. The device aims to assist in prioritizing and triaging chest x-ray images. The standalone software consists of both on-premise and on-cloud modules. The on-premise module interacts with the hospital Picture Archiving and Communication System (PACS) in order to retrieve input DICOM images and de-identify data before sending it to the on-cloud module to process. The on-cloud deep learning algorithms then analyze chest x-rays and output structured reports detailing probabilities of abnormalities in the image. The software is capable of producing a secondary capture DICOM image with AI analysis results to send back to the PACS system or display on MyInspectra web application. The software flags cases with suspected findings, showing passive notification on the work list to notify qualified physicians to urgently review the suspected cases. X-rays without an identified anomaly are placed on the worklist for a routine review, which is the current standard of care. Inspectra CXR does not mark, highlight, or direct user attention to a specific location on the original chest x-ray image. The device generates a secondary image from the original image with an overlay that has to be turned on by qualified physicians when additional information is needed in the clinical review. The device intends to only assist radiologists/trained clinicians to facilitate clinical review of chest x-rays. It does not include clinical or patient historical data or recommends treatments or diagnoses. The final decision has to be provided by attending physicians or radiologists.

Product Owner Name and Location
Perceptra Company Limited, 723, Supakarn Building, Charoen Nakhon, Khlong Ton Sai Sub-district, Khlong San District, Bangkok Metropolis, Postal Code: 10600

Medical device or accessory specifications are as follows:

<table>
<thead>
<tr>
<th>Item</th>
<th>NEWCODE</th>
<th>Product Name</th>
<th>Identifier</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>661064908001266</td>
<td>Inspectra CXR</td>
<td>Version 02.02.01</td>
<td>Artificial Intelligence Software Assisting the Interpretation of Chest Radiographs</td>
</tr>
</tbody>
</table>
Confirmation of Information, Documents or Evidence Accompanying Application for a License, Specification Report Form and Medical Device Registration Form

I am Miss Supitchaya Phupisut operator of Perceptrx Company Limited

Production/Import Facility Registration Form No. GorThor. SorPhor. 26/2565

according to License/ Specification Report Form/Registration Form No. 66-1-2-2-0000204.

I hereby confirm that:

1. This document accompanying submission of an application for a license, specification report form and registration form is a genuine document prepared by the product manufacturer or owner.

2. The information, document or evidence of medical devices accompanying this application for a license, specification report form and registration form is in compliance with the Ministerial Regulation on Application and Issuance of Licenses for Manufacturing or Importing Medical Devices, B.E. 2563 (A.D. 2020), the Ministerial Regulation on Reporting Information and Issuance of Medical Device Manufacturing or Import Specification Report Forms, B.E. 2563 (A.D. 2020), and the Ministerial Regulation on Registration and Issuance of Medical Device Manufacturing or Import Registration Forms, B.E. 2563 (A.D. 2020), and other relevant laws.

3. Labels and Documents Governing Medical Devices
   a. The labels and documents governing medical devices shown was prepared to have complete, accurate and appropriate content according to academic principles.
   b. Preparation of the labels and documents governing medical devices shown was compliant with the Ministry of Public Health Notification on Criteria, Methods and Conditions for Displays of Labels and Documents Governing Medical Devices, B.E. 2563 (A.D. 2020), or the Ministry of Public Health Notification for that medical device and other relevant laws.
   c. The labels and documents governing medical devices shown have content and symbols that are clearly legible and visible. Content displays are not false, exaggerated, falsely claim properties, cause misunderstanding of significant content, mislead others, inaccurate according to academic principles of that medical device, cause people to have unreal expectations of properties and has no content that is pornographic, impolite, arousing or immoral.
   d. The labels and documents governing medical devices shown has been used and will not be changed until permission is granted to make revisions by the Medical Device Control Division, Food and Drug Administration.

If any confirmations I have given is untrue or if I have not complied as I had confirmed, I consent for the Food and Drug Administration to cancel or withdraw the license, specification report form or registration form, depending on the case, and I acknowledge that falsification of documents or displays of false information are criminal acts. If the aforementioned case occurs, I consent to accept that criminal penalty.

I have thoroughly read this confirmation thoroughly with a clear understanding. Therefore, I have placed my signature herein as evidence.

Signed __________________________

Miss Supitchaya Phupisut

Date 13 Month March Year 2023