

	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
	TF_SYCAI MEDICAL_Annex_20	

Technical file

Annex 20: Product labelling


	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
		TF_SYCAI MEDICAL_Annex_20

1. Index

1. Index..... 2

2. Version control 3

3. Label 5

	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
		TF_SYCAI MEDICAL_Annex_20

2. Version control

Cause of review	Date	Version
First version	24/02/2022	001
Second version <ul style="list-style-type: none"> • Label has been updated according to the last version of IFU. 	18/10/2022	002
Third version: <ul style="list-style-type: none"> • Serial Number updated to the last release (SYCAI Medical SWR2.0.1) • Date of manufacture added • NANDO code updated 	20/12/2022	003
Fourth version: <ul style="list-style-type: none"> • Updated information for new release SYCAI Medical SWR2.1.0 • Removed reference to ubuntu 16.04 in the installation part 	17/02/2023	004
Fifth version: <ul style="list-style-type: none"> • Updated information for new release SYCAI Medical SWR2.2.0 • Removed reference to viewer and shared desktop • CC-72: updated intended use or purpose. Removed reference to “cross-sectional imaging tests” and replaced with “CT scans”. 	27/11/2023	005
Sixth version: <ul style="list-style-type: none"> • Updated information for new release SYCAI Medical SWR2.3.0 • CC-98: <ul style="list-style-type: none"> ○ Reference of mail info@sycaitechnologies.com replaced with a link to service desk platform • Update regarding CC-107: accessories. 	17/05/2024	006
Seventh version: <ul style="list-style-type: none"> • Updated information for new release SYCAI Medical SWR2.4.0 	18/06/2024	007
Eight version: <ul style="list-style-type: none"> • CC-118: <ul style="list-style-type: none"> ○ Update of office’s address ○ Update CE mark symbol • RAQA-209: <ul style="list-style-type: none"> ○ Updated information for new release SYCAI Medical SWR2.4.1 	12/09/2024	008






TECHNICAL DOCUMENTATION

PRODUCT LABELLING

Version: 008

Date: 12/09/2024




TF_SYCAI
MEDICAL_Annex_20

Written by:  COO 12/9/24	Revised by:  PRRC 12/09/2024	Approved by:  CEO 12/9/24
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	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
TF_SYCAI MEDICAL_Annex_20		

3. Label

	
<p>SYCAI MEDICAL es un dispositivo médico software, basado en inteligencia artificial, que ayuda a los radiólogos en la detección y caracterización de hallazgos radiológicos en el páncreas en imágenes de tomografías computarizadas de pacientes adultos.</p> <p>Los usuarios previstos son radiólogos.</p>	
	<p>SYCAI TECHNOLOGIES S.L. Calle Llacuna 156-162, 2ª planta, oficina 203, 08018, Barcelona, Cataluña, España (+34) 623 02 81 48 https://sycaimedical.com/ support@sycatechnologies.com</p>
	<p>Producto sanitario fabricado en España. Fecha de fabricación: 2024-09</p>
	<p>Producto sanitario software</p>
	<p>(01) 08499993235353 (20)020401 (8012)POYYNNN</p> <p>UDI is assigned for each production order when generating the installation package, YY corresponds to the year, NNN to the production order number.</p>
	<p>Consulte las instrucciones de uso antes de utilizar este producto. Estas se proporcionan en formato electrónico.</p>

	<p>SYCAI Medical®</p>
	<p>SYCAI Medical SWR2.4.1</p>
	<p>Precauciones y alertas</p> <ul style="list-style-type: none"> Las decisiones de gestión de pacientes no deben basarse únicamente en los resultados de SYCAI Medical®. Este equipo debe tener conectividad con PACS donde se almacenan los estudios. SYCAI Medical está destinado a ser utilizado con los siguientes accesorios: RAIM VIEWER 2.8 (SNXXXX2.8)(enlace a sus instrucciones de uso) <p>En caso de observar un funcionamiento incorrecto del software avise al fabricante lo antes posible: support@sycatechnologies.com. El fabricante procederá en consecuencia. Cualquier incidente grave debe ser informado a SYCAI TECHNOLOGIES S.L. así como a la Autoridad Nacional Competente del país.</p> <p>Efectos secundarios indeseables. No se conocen ni se prevén efectos secundarios indeseables relacionados específicamente con el uso del software.</p> <p>Pacientes objetivo SYCAI Medical® está destinado a ser usado en pacientes adultos (mayores de 18 años). SYCAI Medical® está destinado a ser utilizado con todos los pacientes sometidos a una prueba de TC abdominal.</p> <p>Criterio de inclusión de pacientes</p> <ul style="list-style-type: none"> Pacientes mayores de 18 años. Pacientes de ambos sexos. Pacientes que se hayan sometido a una tomografía computarizada (TC) abdominal. <p>Criterio de exclusión de pacientes</p> <ul style="list-style-type: none"> Pacientes menores de 18 años. Mujeres embarazadas. Pacientes con pancreatectomía.

	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
TF_SYCAI MEDICAL_Annex_20		


	<ul style="list-style-type: none"> Imágenes de TC abdominal que muestren menos del 40% de la lesión quística pancreática. Imágenes de TC abdominal con mala calidad, imagen borrosa o defectuosa. Imágenes de TC abdominal con presencia de material metálico o radiopaco. Imágenes de TC abdominal de pacientes rotados más de 10°. Imágenes de TC abdominal con marcas de movimiento.
	<p>Producto sanitario software en cumplimiento con los requisitos establecidos en la Regulación Europea (EU) MDR 2017/745.</p>

Figure 1: Product label in Spanish.

	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	
	Version: 008	Date: 12/09/2024
		TF_SYCAI MEDICAL_Annex_20

	
<p>SYCAI MEDICAL is a medical device software, based on artificial intelligence, that assists radiologists in the detection and characterization of radiological findings in the pancreas on CT scans of adult patients. The intended users are radiologists.</p>	
	<p>SYCAI TECHNOLOGIES S.L. 156-162 Llacuna Street, 2nd floor, Office 203, 08018, Barcelona, Catalonia, Spain (+34) 623 02 81 48 https://sycaimedical.com/ support@sycaitechnologies.com</p>
	<p>Medical device manufactured in Spain. Manufacture date: 2024-09</p>
	<p>Medical device software</p>
	<p>(01) 08499993235353 (20)020401 (8012)POYYNNN</p> <p>UDI is assigned for each production order when generating the installation package, YY corresponds to the year, NNN to the production order number.</p>
	<p>Read the instructions for use before using this product. These are provided in electronic format.</p>
	<p>SYCAI Medical®</p>



SYCAI Medical SWR2.4.1



Precautions and alerts

- Patient management decisions should not be based solely on test results of SYCAI Medical®.
- This equipment must have connectivity with the PACS where the studies are stored.
- SYCAI Medical is intended to be used with the following accessories: [RAIM VIEWER 2.8 \(SNXXX2.8\)](#)(link to its Instructions for Use)

In case of observing an incorrect operation of the medical device, notify the manufacturer as soon as possible: support@sycatechnologies.com. The manufacturer will proceed accordingly. Any serious incident must be reported to SYCAI TECHNOLOGIES S.L. as well as the National Competent Authority of the country.

Undesirable side effects

No undesirable side effects specifically related to the use of the software are known or anticipated.

Undesirable side effects

No undesirable side effects specifically related to the use of the software are known or anticipated.

Targeted patients

SYCAI MEDICAL is intended to be used with adult patients (18 years old and above). SYCAI MEDICAL is intended to be used with all patients undergoing an abdominal CT imaging test.

Inclusion criteria for patients

- Patients older than 18 years old.
- Patients of both sexes.
- Patients who have undergone an abdominal CT scan.

Exclusion criteria for patients

- Patients younger than 18 years old.
- Pregnant women.
- Patients with pancreatectomy.
- Abdominal CT images showing less than 40% of the pancreatic cystic lesion.
- Abdominal CT images with poor image quality, blurred or defective image.
- Abdominal CT images with the presence of metal/radiopaque material.
- Abdominal CT images with rotated patients (>10 °).
- Abdominal CT images with movement stripes.

	TECHNICAL DOCUMENTATION	
	PRODUCT LABELLING	Version: 008
		Date: 12/09/2024
		TF_SYCAI MEDICAL_Annex_20

	<p>Software medical device in compliance with the requirements established by the European Regulation (EU) MDR 2017/745.</p>
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Figure 2: Product label in English.