February 21, 2023

MEDICAL DEVICE RECALL **PCRopsis RVD products & accessories.**

Dear Device Customer/Distributor,

The purpose of this letter is to advise you that Entopsis Inc., FL, USA is voluntarily recalling the following PCRopsis RVD products & accessories shipped/received before February 8th 2023 due to misleading label statements on the product label.

The voluntary recall is done at the advice of the Food and Drug Administration (FDA) that the labeling of PCRopsis devices does not accurately reflect the research status of the devices. Therefore, there is a potential risk for improper use of the PCRopsis devices. PCRopsis devices are designed for nucleic acid extraction from a variety of biological samples and do not provide any diagnostic information.

Frequency of failures and complaints:

At this time, we are not aware of any adverse reactions associated with device failure and have not received any complaints related to the performance or quality of PCRopsis devices.

Risk to Health:

Device failure caused due to improper use may affect the downstream applications sought after nucleic acid extraction,for example, nucleic acid detection assays (Polymerase chain reactions or nucleic acid sequencing).

How to recognize that the device may fail ?.- The assays designed for nucleic acid detection after extraction will not yield the expected results using established samples; for example positive controls used for detection will not yield the proposed results (i.e. positive signal).

Actions/Instructions to be taken by the Customer/User:

Entopsis Inc., requests that the product lots listed below - shipped/received before February 8th, 2023 be promptly discontinued from use and discarded from inventory as per your non-hazardous waste disposal plan.The labeling of PCRopsis products was revised on February 8th, 2023. Updated statements of intended use and revised instructions for use are available on www.pcropsis.com. If you are currently using or intend to use the PCRopsis product lots affected by this recall please contact us at team@entopsis.net or 1-888-407-5070 (Monday to Friday 9.00 AM to 4.30 PM Eastern Time) to request a replacement. Please acknowledge the removal of affected product lots by filling out the online survey powered by SurveyMonkey.

Product and Distribution Information: February 8th, 2023

Product and Distribution Information Table					
Product Names, Unique Device Identifier (if applicable)	Manufacturer's Product Number/Catalog Number	Lot	Manufacturing/Distribution Dates	Expiration Date (MM/YYYY)	Quantity Shipped
PCRopsis(TM) RVD w/ Enh. (1ml) (25ml) (100ml)	B550783360010	18	Pre February 8th 2023	05/2023	47
		20		07/2023	236
		21		07/2023	82
	B550783360250	18		05/2023	8
		20		07/2023	21
		21		07/2023	2
	B550783361000	21		07/2023	1
PCRopsis(TM) RVD-RT (1ml) (25ml) (100ml)	B550783780010	4	Pre February 8th 2023.	02/2023	58
		7		07/2023	35
	B550783780250	6		06/2023	1
	B550783781000	7		07/2023	3
PCRopsis(TM) Support (1ml) (0.25ml) (25ul)	B5507870010	4	Pre February 8th 2023.	05/2023	11
	B5507870020	4		05/2023	43
		5		07/2023	35
	B5507870030	5		07/2023	5
PCRopsis(TM) Activator (1.5ml) (0.5ml)	B5502280010	3	Pre February 8th 2023.	05/2023	10
		4		07/2023	1
	B5502280020	3		05/2023	11
		4		07/2023	19
		5		04/2023	11
PCRopsis(TM) Lysis Beads (x25) (x25) (x50) (25g) (1000g)	B5505970002	2	Pre February 8th 2023.	05/2024	18
		3		06/2024	5
	B5505978252	5		06/2024	3
	B5505978503	2		05/2024	3
	B55059700250	2		05/2024	16
		3		06/2024	49
		4		06/2024	39
		5		06/2024	229
	B55059710000	4		06/2024	1

PCRopsis BCSNano (1mL)	B5502276001	3	Pre February 8th 2023.	11/2023	3
PCRopsis Buccal (1mL)	B550282001	4	Pre February 8th 2023.	08/2023	6

Entopsis Inc., has revised the labeling and instructions of use on February 8th 2023. Updated statements of intended use and instructions of use are available at www.PCRopsis.com.

Contact us at team@entopsis.net or 1-888-407-5070 - Monday to Friday 9.00 AM to 4.30 PM US Eastern Time (GMT -5) with any questions you may have. **Please acknowledge the recall action by filling the online acknowledgement survey form by scanning the QR code.** If you would like to request a replacement for affected lots currently in your use contact us.

Authorized by:

Name: (Print) Obdulio Piloto

Signature: _____

Title: CEO

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

https://www.surveymonkey.com/r/WB8VPG2

Scan the code above to complete the required

Acknowledgement and Receipt Form