EU MDR DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

This declaration of conformity is issued under the sole responsibility of VacSax Ltd. in compliance to Article 19 of EU MDR 2017/745. We hereby declare that the medical device specified below meet the provision of the Annex IV of Regulation EU MDR 2017/745 for medical devices.

Manufacturers Name: VacSax limited

Manufacturers Address : Western Wood Way, Langage Science Park, Plymouth PL7 5BG, United Kingdom

SRN (Single Registration Number) : GB-MF-000003621

Authorized Representative Name: DCC (Fannin) Limited

Authorized Representative Address: Leopardstown, Dublin 18, Ireland

Device Generic description: Suction system filter, tissue.

Intended use: The devices are intended to be used with disposable suction liners for the separation of tissues and other matter from aspirate, not for IVD use.

Classification with rule number: Class I as per MDR Annex VIII rule 1

Basic UDI: 5055761662064ZN

Unit of use DI	UDI-DI (Primary packaging)	SKU	Product description
5055761602654	5055761600148	9410-001	TISSUE COLLECTION DEVICE
5055761603903	5055761601718	9410-004	TISSUE COLLECTION DEVICE (NO RETAINING RING)
5055761603514	5055761603521	9410-005	TISSUE COLLECTION DEVICE -NO INNER CARTON
5055761603606	5055761603590	9410-006	TISSUE COLLECTION DEVICE
5055761602928	5055761600377	9970-007	FILTER SOCK

This declaration is valid for five years from approval. This document has been authorised by persons of regulatory responsibility appointed by VacSax Limited.

Authorised by:

Date: 13th May 2021

R. Saunders – Engineering manager

Authorised by:

Date: 13th May 2021

G. Harper – Quality manager

On behalf of VacSax Limited