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: Bodily fluid solidifier

Intended use: The solidification of liquid medical waste to aide disposal.

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

Basic UDI: 505576166294736

Unit of use DI	UDI-DI (primary packaging)	SKU	Product description
5055761602814	5055761600759	9820-036	PREGEL SACHET 36g
5055761602814	5055761600360	9820-720	PREGEL SACHET 36g
5055761602838	5055761600117	9830-008	PREGEL SACHET 8g
5055761602807	5055761601275	9830-020	PREGEL SACHET 20g
5055761602845	5055761600568	9830-100	PREGEL BOTTLE 36g
5055761602852	5055761600179	9830-200	PRE-GEL BOTTLES 72g
5055761602869	5055761600988	9830-300	PREGEL BOTTLE 108g
5055761600339	5055761600339	9830-400	PREGEL TUB 4kg
5055761602876	5055761601152	9830-750	PREGEL BOTTLE 750 g

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