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 tubing, single use

Intended use: Suction tubing for the transfer of fluids between suction liners.

Classification with rule number: Class I as per MDR Annex VIII rule 2

Basic UDI: 50557616167792E

Unit of use DI	UDI-DI	SKU	Description
5055761602647	5055761600292	4310-021	CASCADE TUBING SET
5055761602647	5055761600476	4310-621	CASCADE TUBING SET
5055761603774	5055761603781	4310-023	CASCADE TUBING SET
5055761602425	5055761602425	9210-090	PATIENT TUBING ADAPTOR
5055761602555	5055761601091	9910-040	PATIENT PORT ADAPTER

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