



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, Langleigh 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 liner canister

Intended use: Intended for use in healthcare environments where the removal and disposal of fluids using suction is required, requires the use of inner disposable suction liner. For use with systems generally complying with ISO 10079.

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

Basic UDI: 50557616449432N

Unit of use DI	SKU	Product description
5055761602081	3833-041	BACTICLEAR 3 LITRE VEE MOUNT CANISTER W/BYPASS
5055761602098	3833-042	BACTICLEAR 3 LITRE PARALLEL MOUNT CANISTER W/BYPASS
5055761602104	3833-045	BACTICLEAR 3 LITRE EUROPEAN MOUNT CANISTER W/BYPASS
5055761602586	3833-054	FUMEVAX CANISTER
5055761602111	3833-055	BACTICLEAR CASCADE 2 LITRE VEE CANISTER W/BYPASS
5055761602128	3833-058	BACTICLEAR CASCADE 2 LITRE PARALLEL CANISTER W/BYPASS
5055761602135	3833-090	BACTICLEAR CANISTER 2000ml VEE MOUNT PRINTED
5055761602142	3833-098	BACTICLEAR CANISTER 2000ml PARALLEL MOUNT
5055761602159	3833-132	BACTICLEAR CANISTER 1000ml VEE MOUNT
5055761602166	3833-134	BACTICLEAR CANISTER 1000ml PARALLEL MOUNT
5055761602173	3833-149	BACTICLEAR CANISTER 2000ml EUROPEAN MOUNT
5055761602180	3833-153	BACTICLEAR CANISTER 1000ml EUROPEAN MOUNT
5055761602197	3833-165	BACTICLEAR 2000ML EUROPEAN MOUNT CANISTER W/BYPASS
5055761601817	3833-188	BACTICLEAR WARD CANISTER 2000ML with BYPASS HOLE
5055761601800	3833-190	BACTICLEAR WARD CANISTER 1000ML with BYPASS HOLE
5055761603804	3833-210	BACTICLEAR CANISTER PARALLEL 1000ML with BYPASS HOLE
5055761603798	3833-212	BACTICLEAR CANISTER EURO PARALLEL 1000ML with BYPASS HOLE

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:

Authorised by:

Page 1 of 1

Date: 13th May 2021

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R. Saunders – Engineering manager

G. Harper – Quality manager

On behalf of VacSax Limited