



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, Lantage 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: Disposable suction liner

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

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

Basic UDI: 50557616449422L

Unit of use DI	UDI-DI (primary packaging)	SKU	Product description
5055761602463	5055761603378	EAL-203	VACSAX BACTICLEAR Liner 2L CASCADE
	5055761601978	VAL-203	VACSAX BACTICLEAR Liner 2L CASCADE
	5055761602036	VAL-263	VACSAX BACTICLEAR CASCADE LINER 2000ml
5055761602470	5055761601879	GAL-213	GELSAX BACTICLEAR Liner 2000 ml CASCADE
	5055761601909	GAL-263	GELSAX BACTICLEAR CASCADE LINER 2000ml
5055761602692	5055761601749	9640-102	1000ml NON-SAMPLE PORT LINER WITH GEL
5055761602708	5055761601756	9640-103	1000ml NON-SAMPLE PORT LINER WITHOUT GEL
5055761602715	5055761601763	9640-201	2000ml NON-SAMPLE PORT LINER WITH GEL
5055761602777	5055761602289	9620-101	VACSAX BACTICLEAR LINER 1000ml 8.5 PORT
	5055761602241	9910-340	VACSAX BACTICLEAR LINER 1000ml 8.5 PORT
	5055761601954	VAL-161	VACSAX BACTICLEAR 1000ML
5055761602784	5055761602234	9810-101	SUCTION LINER 8.5mm PORT WITH GEL
	5055761603873	EAL-101	SUCTION LINER 8.5mm PORT WITH GEL
	5055761603866	TAL-101	SUCTION LINER 8.5mm PORT WITH GEL
5055761602791	5055761602272	9910-510	FUMEVAX LINER
5055761602883	5055761601770	BWL-101	BACTICLEAR WARD 1000ML LINER
5055761602890	5055761601787	BWL-201	BACTICLEAR WARD 2000ML LINER
5055761602905	5055761602432	BWG-101	BACTICLEAR WARD GEL 1000ML LINER
5055761602913	5055761602449	BWG-201	BACTICLEAR WARD GEL 2000ML LINER
5055761603002	5055761601930	VAL-102	VACSAX BACTICLEAR 1000ML WIDE BORE

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:

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Date: 20th May 2021

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Version 2

R. Saunders – Engineering manager

G. Harper – Quality manager

On behalf of VacSax Limited

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Unit of use DI	UDI-DI (primary packaging)	SKU	Product description
5055761603019	5055761601947	VAL-104	VACSAX BACTICLEAR SAMPLE PORT LINER 1000 ml
5055761603026	5055761601961	VAL-201	VACSAX BACTICLEAR LINER 2L Standard
	5055761602012	VAL-206	VACSAX BACTICLEAR LINER 2000ml
	5055761602029	VAL-261	VACSAX BACTICLEAR 2000 ml
5055761603033	5055761601985	VAL-202	VACSAX BACTICLEAR LINER 2L WIDE BORE
5055761603040	5055761601992	VAL-204	VACSAX BACTICLEAR SAMPLE PORT LINER 2000 ml
	5055761603392	VAL-264	VACSAX BACTICLEAR SAMPLE PORT 2000 ml
5055761603057	5055761601855	GAL-211	GELSAX BACTICLEAR LINER 2000 ml Standard
	5055761601886	GAL-260	GELSAX BACTICLEAR LINER 2000 ml
	5055761601893	GAL-261	GELSAX BACTICLEAR LINER 2000 ml
	5055761603859	TAL-211	GELSAX BACTICLEAR LINER 2000 ml Standard
5055761603064	5055761601862	GAL-212	GELSAX BACTICLEAR LINER 2000 ml WIDE BORE
5055761603569	5055761603576	9640-213	2000ml NON-SAMPLE PORT CASCADE LINER WITH GEL
5055761603071	5055761602005	VAL-205	VACSAX BACTICLEAR SAMPLE PORT CASCADE LINER 2000 ml
	5055761603408	VAL-265	VACSAX BACTICLEAR SAMPLE PORT CASCADE 2000 ml

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Unit of use DI	UDI-DI (primary packaging)	SKU	Product description
5055761603088	5055761602043	VAL-301	VACSAX BACTICLEAR 3000 ml STANDARD
5055761603095	5055761602050	VAL-303	VACSAX BACTICLEAR 3000 ml CASCADE
5055761603101	5055761602067	VAL-304	VACSAX BACTICLEAR SAMPLE PORT LINER 3000 ml
5055761603118	5055761602074	VAL-306	VACSAX BACTICLEAR SAMPLE PORT CASCADE LINER 3000 ml
5055761603125	5055761601916	GAL-311	GELSAX BACTICLEAR STANDARD 3000 ml
5055761603132	5055761601923	GAL-313	GELSAX BACTICLEAR CASCADE 3000 ml
5055761603460	5055761603453	GAL-112	GELSAX BACTICLEAR SUCTION LINER 1000mm WITH GEL
5055761603477	5055761603439	EAL-211	2000 ml GELSAX BACTICLEAR STANDARD
5055761603484	5055761603422	EAL-213	2000 ml GELSAX BACTICLEAR CASCADE

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