SANISURE Solution Based Innovation Specifications sheet	220000-01 20L PC PharmaTainer	Doc #	Rev #
		LUXSPE-43	4
		Approval date	
		13 March 2026	

20L PC PharmaTainer	Catalogue number - 220000-01

Bottle part #	120000	USP Class VI	ADCF	DMF #
Bottle material	SaniSure resin code 002	Yes	Yes	1562
Nominal volume	20.000ml			
Brim Capacity	23.120ml			

		Tolerance
Bottle dimensions w/o caps	H500 x W256 x 256 mm	+/- 3.1mm
Bottle weight w/o caps	984.0g	+/- 3%
Bottle thread O.D	63.77mm	+/- 0.3mm
Bottle neck I.D	54.5mm	+/- 0.3mm

Graduation	2000ml - 20.000ml	1000ml intervals	Tolerance	
			+/- 5%	
Sterility	C60 y irradiated X-Ray	SAL10-6	Internal Surface	
			464418 mm²	
Endotoxin	No detectable Endotoxin	Certified by lot	Internal Volume	
			22402630 mm³	
Bottle decoration	Graduation scale	Lot number	Expiration date	Data Matrix
Bottle colour	Clear			

Traceability	Lot Number	Data Matrix	Serial Number

Closure part #	300070C2-99	Closure colour	Natural	
Closure Material	SaniSure resin code 003	USP Class VI	ADCF	DMF #
		Yes	Yes	1646
Closure weight	24g	Tolerance		
		+/- 1g		
Closure Dimensions	H 28mm O.D 70.0mm	Tolerance		
		+/- 0.3mm		

Packaging details	Carton	Level 3 - Carton liner	Level 2	Level 1 - Sterile Barrier
	4mm single corrugate, top and base protection sheet	50µ LDPE monolayer film tape sealed bag	100µm LDPE monolayer film Heat sealed bag	120µm PE/PA/PE multilayer film vacuum bag heat sealed

Carton dimensions	L 590 - W 330 - H 570 mm	Carton weight	Units per carton	Units per sterile barrier
		3.5kg	2	1 (single pack)

Palettisation	Dimensions L x W x H	Weight (inc. Pallet)	Carton per pallet	Density
Industry pallet	1200x1000x1850mm	83kg	18	0.04

RAW MATERIAL SPECIFICATION

PRODUCT DESCRIPTION

Material Description:	20L Pharmatainer Bottle, Sterile
Supplier Part Number:	220000-01

OVERVIEW

The purpose of this Raw Material Specification is to provide key regulatory information frequently requested by customers on the above-mentioned product. The information contained herein is offered in good faith and is accurate as of the revision and date shown on this specification.

Specification data is based on information provided by our suppliers and other readily available information. Final conditions and methods for use of our single-use products are beyond our control, thus this information should not be substituted for customer's own regulatory determinations and suitability tests to ensure that the use of the products is legally compliant, safe, effective, and satisfactory for the customers intended use.

GENERAL INFORMATION

Material of Construction (MOC):	PC
Product Classification:	Bottle
Is material Halal:	No Information Available
MSDS/SDS:	Not Applicable

RAW MATERIAL PROPERTIES

Is material GAMMA stable?	Yes
GAMMA Tolerance:	25Gy - 50kGy
Autoclavable:	No Information Available
Resin:	Lexan HPS9NEU-1H1125
Contains Heavy Metals:	No Information Available

MATERIAL COMPOSITION

Free From

Allergens:	Yes
Bisphenol A (BPA):	No
Quantity in PPM:	less than 100 milligrams per kilogram polycarbonate
Gluten:	Yes
Genetically Modified Organisms (GMO):	Yes
Phthalate:	Yes
Latex:	Yes
Melamine:	Yes
Conflict Minerals:	Yes
Residual Solvent:	Yes
Ozone Depleting Chemicals (ODCs):	No Information Available
Nitrosamine:	Yes

DNase/RNase: No Information Available

Origin

Country of Origin: European Union
Animal Derivative Component Free: Yes
EMEA 410 Compliant: Not Applicable

SUPPLY CHAIN

Manufacturer: SaniSure SA
Manufacturer Address: Rue Heierchen 16 , Bascharage, Luxemburg 4940
Shelf Life (years): 5
Storage Conditions: The shelf life of these products is dependent upon the storage conditions. In general, it is best to store these products in a cool dry environment (ambient conditions) shielded from direct sunlight and stored in the original packaging until ready to use.

REGULATORY

Regulatory Lists:

RoHs	REACH/SVHC	CA Prop 65	CONEG	*WEEE
✔	✔	NIA	✔	NIA

*WEEE = Waste Electrical & Electronic Equipment

USP Class VI (USP 88): Yes
USP 87: Yes
ISO 10993 - Biocompatibility: Yes
Section(s): 5, 6, 10, 11
Extractables:

USP 661	USP 665	BPOG	FDA
✔	✔	NIA	NIA

USP 85 - Endotoxin: Yes
USP 788 - Particulates: Yes
Drug Master File: Yes
DMF number: 1562
FDA 21CFR 177: Yes
Section(s): 1580
Contains PFAS: No
Legend: NA = Not Applicable
NIA = No Information Available

OTHER

Additional information can be found on the manufacturers specification which is included with this specification.

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