

TECHNICAL DATASHEET

Product Name : C3 Emptying Bag w/SAP by Curas™
 Brand : CURAS®
 Category : UROLOGY™
 Range : Drainage Bags
 Group/Cluster : C3 Emptying Bags



REF	Description	Capacity	Flexi-Funnel™ Size	DEHP
20460	C3 Emptying Bag w/SAP by Curas™, 2L, Dual-NRV System (incl. Spigot), Flexi-Funnel™, Cross-Hanger™, Non-DEHP, CleanPak™, WardPak™	2L	Standard	Non-DEHP
20462	C3 Emptying Bag w/SAP by Curas™, 4L, Dual-NRV System (incl. Spigot), Flexi-Funnel™, Cross-Hanger™, Non-DEHP, CleanPak™, WardPak™ PLUS	4L	Standard	Non-DEHP
20465	C3 Emptying Bag w/SAP by Curas™, 1.5L, Dual-NRV System (incl. Spigot), Medium Flexi-Funnel™, Cross-Hanger™, Non-DEHP, CleanPak™, WardPak™	1.5L	Medium	Non-DEHP
20469	C3 Emptying Bag w/SAP by Curas™, 2L, Dual-NRV System (incl. Spigot), Medium Flexi-Funnel™, Cross-Hanger™, Non-DEHP, CleanPak™, WardPak™ PLUS	2L	Medium	Non-DEHP
20470	C3 Emptying Bag w/SAP by Curas™, 2L, Dual-NRV System (incl. Spigot), Flexi-Funnel™, Cross-Hanger™, DEHP-Free, CleanPak™, WardPak™	2L	Standard	DEHP Free

Europe
 Curas Ltd.
 Country Gates, Ashton Rd.
 Bristol BS3 2JH
 England
 Phone +44 7796 338 585

Asia Pacific
 69A-B Raja Uda Business
 Centre Road 4, 12300
 Penang, Malaysia

Phone +60 4 314 0525
 Fax +60 4 314 0625

Worldwide
 info@curas.com
 www.curas.com

Description

Disposable C3 Emptying Bag integrated with Flexi-Funnel™ for easy connection to various urine bag with bottom outlet. It comes with Cross-Hanger™ to better secure the connection. These products are latex free and are available in the following options/ features:

- 1.5L, 2L or 4L capacity
- Standard or medium size of Flexi-Funnel™
- Non-DEHP or DEHP Free material

Intended Use

Curas C3 Emptying Bags are used for draining and emptying urine from drainage bag systems. It is most suitable for collection of biohazard and cytotoxic waste. It can also be used to collect bodily fluids. The C3 Emptying Bag helps to reduce risk of infection by providing a closed system during the urine collection. It is suitable for short-duration use and is intended for single use only. The SAP by Curas™ (Fluid Absorber) included to provide rapid, consistent absorption of bodily fluids and other liquids by converting these fluids to a firm, non-spill gel.

TDS/2046X_2047X/C3WSAP/111024/03

Specifications

Product Capacity	: 1.5L, 2L, 4L
Bag Film Thickness	: 0.115mm (REF 20460, REF 20465 and REF 20469) 0.25mm (REF 20462) 0.110mm (REF 20470)
Connector	: Flexi-Funnel™, Medium Flexi-Funnel™
Connector Shore Hardness	: 63-65A (REF 20460 and REF 20462), 70-75A (REF 20465 and REF 20469)

Composition	:	<table border="1"> <thead> <tr> <th>No.</th><th>Component Name</th><th>Material</th></tr> </thead> <tbody> <tr> <td>1.</td><td>Funnel</td><td>Non-DEHP PVC (Plasticizer: TOTM/DINP)</td></tr> <tr> <td>2.</td><td>Bag</td><td>Non-DEHP PVC (Plasticizer: TOTM)</td></tr> <tr> <td>3.</td><td>Shoelace</td><td>Dacron</td></tr> <tr> <td>4.</td><td>Catheter Spigot</td><td>REF 20460, REF 20465 : PE REF 20462, REF 20469, REF 20470 : PP</td></tr> <tr> <td>5.</td><td>Non-Return Valve</td><td>Non-DEHP PVC (Plasticizer: TOTM)</td></tr> <tr> <td>6.</td><td>SAP</td><td>-</td></tr> <tr> <td>7.</td><td>Filter</td><td>PA (Applicable for REF 20462 only)</td></tr> <tr> <td>8.</td><td>Platic Sheet</td><td>ABS (Applicable for REF 20462 only)</td></tr> </tbody> </table>	No.	Component Name	Material	1.	Funnel	Non-DEHP PVC (Plasticizer: TOTM/DINP)	2.	Bag	Non-DEHP PVC (Plasticizer: TOTM)	3.	Shoelace	Dacron	4.	Catheter Spigot	REF 20460, REF 20465 : PE REF 20462, REF 20469, REF 20470 : PP	5.	Non-Return Valve	Non-DEHP PVC (Plasticizer: TOTM)	6.	SAP	-	7.	Filter	PA (Applicable for REF 20462 only)	8.	Platic Sheet	ABS (Applicable for REF 20462 only)
No.	Component Name	Material																											
1.	Funnel	Non-DEHP PVC (Plasticizer: TOTM/DINP)																											
2.	Bag	Non-DEHP PVC (Plasticizer: TOTM)																											
3.	Shoelace	Dacron																											
4.	Catheter Spigot	REF 20460, REF 20465 : PE REF 20462, REF 20469, REF 20470 : PP																											
5.	Non-Return Valve	Non-DEHP PVC (Plasticizer: TOTM)																											
6.	SAP	-																											
7.	Filter	PA (Applicable for REF 20462 only)																											
8.	Platic Sheet	ABS (Applicable for REF 20462 only)																											

Country of Origin : China (REF 20460, REF 20462, REF 20465 and REF 20469)
Thailand (REF 20470)

Sterility : Non-sterile

Shelf Life : 5 years

Risk Class : Class I

Classification Info

Global Trade Item Number (GTIN)	20460	05051400204609
	20462	05051400204623
	20465	05051400204654
	20469	05051400204692
	20470	05051400204708
Global Medical Device Nomenclature (GMDN)		58917
European Medical Device Nomenclature (EMDN)		A06030301

Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

Technical Test Results

Test article name : C3 Emptying Bags w/SAP by Curas™
 Test article Sterilization : Non-sterile

No.	Test Name	References	Test Result	
1	Phthalates Contents Analysis	With reference to EPA 3550C:2007 and EPA 2870D: 2007, Extraction with solvent, analysed by Gas Chromatography Mass Spectrometer.	The test result showed that the test article extract complies with the limits as set by RoHS D directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.	PASS
2	Urine Collection Bags	Urine collection bags Part 1: Vocabulary (ISO 8669-1:1988) Urine collection bags Part 2: Requirements and test methods (ISO 8669-2:1996)	The test result showed that the test article complies with the standard requirement as stated in ISO 8669.	PASS

Standards & Guidelines

- EN ISO 13485:2016
- MDR 2017/745, Class I
- ISO 9001:2015
- EN ISO 14971:2019
- ISO 8669-1:1988
- ISO 8669-2:1996
- EN ISO 10993-10:2021
- EN 62366:2008
- EN ISO 15223-1:2021
- ISO 20417:2021
- EN ISO 14698-1:2003
- EN ISO 14698-2:2003
- EN ISO 10993-1:2018
- EN ISO 10993-5:2009
- EN ISO 10993-7:2008/AC:2009

Europe
 Curas Ltd.
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 Bristol BS3 2JH
 England
 Phone +44 7796 338 585

Asia Pacific
 69A-B Raja Uda Business
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 Penang, Malaysia

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 Fax +60 4 314 0625

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 info@curas.com
 www.curas.com

Packaging

REF 20460

	CleanPak™	WardPak™	Carton
Packaging Dimension	225mm x 210mm x 16mm	225mm x 230mm x 135mm	470mm x 460mm x 290mm
Material	HDPE	Corrugated box	Corrugated carton
Weight/pc of Packaging	~ 3.6g	~ 143g	~ 1kg
Quantity	1 pc/bag	25 pcs/box	200 pcs/carton
Gross Weight	~ 64g	~ 1.6kg	~ 13kg

TDS/2046X_2047X/C3wSAP/111024/03

REF 20462

	CleanPak™	WardPak™	Carton
Packaging Dimension	270mm x 250mm x 30mm	270mm x 250mm x 140mm	470mm x 460mm x 290mm
Material	HDPE	Corrugated box	Corrugated carton
Weight/pc of Packaging	~ 4.1g	~ 160g	~ 1kg
Quantity	1 pc/bag	25 pcs/box	160 pcs/carton
Gross Weight	~ 100g	~ 4kg	~ 17kg

REF 20465

	CleanPak™	WardPak™	Carton
Packaging Dimension	225mm x 195mm x 16mm	225mm x 220mm x 135mm	460mm x 450mm x 280mm
Material	HDPE	Corrugated box	Corrugated carton
Weight/pc of Packaging	~ 3.3g	~ 143g	~ 1kg
Quantity	1 pc/bag	25 pcs/box	200 pcs/carton
Gross Weight	~ 47g	~ 1.4kg	~ 13kg

REF 20469

	CleanPak™	WardPak™	Carton
Packaging Dimension	225mm x 210mm x 16mm	225mm x 230mm x 135mm	685mm x 245mm x 290mm
Material	HDPE	Corrugated box	Corrugated carton
Weight/pc of Packaging	~ 3.5g	~ 143g	~ 1kg
Quantity	1 pc/bag	25 pcs/box	150 pcs/carton
Gross Weight	~ 55g	~ 1.5kg	~ 11kg

REF 20470

	CleanPak™	WardPak™	Carton
Packaging Dimension	225mm x 210mm	240mm x 190mm x 120mm	600mm x 265mm x 270mm
Material	HDPE	Corrugated box	Corrugated carton
Weight/pc of Packaging	~ 3.5g	~ 130g	~ 1kg
Quantity	1 pc/bag	25 pcs/box	150 pcs/carton
Gross Weight	~ 41g	~ 1.4kg	~ 10kg

Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

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Fax +60 4 314 0625

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info@curas.com
www.curas.com

Recommended Product Storage

- Store at dry, clean, and well-ventilated area at room temperatures between 15° to 25°C (59°- 77°F).
- Do not expose the product to sunlight, UV light, as it will change properties of the product.
- Keep away from moisture and store at dry place with relative humidity levels between 30-60% RH.

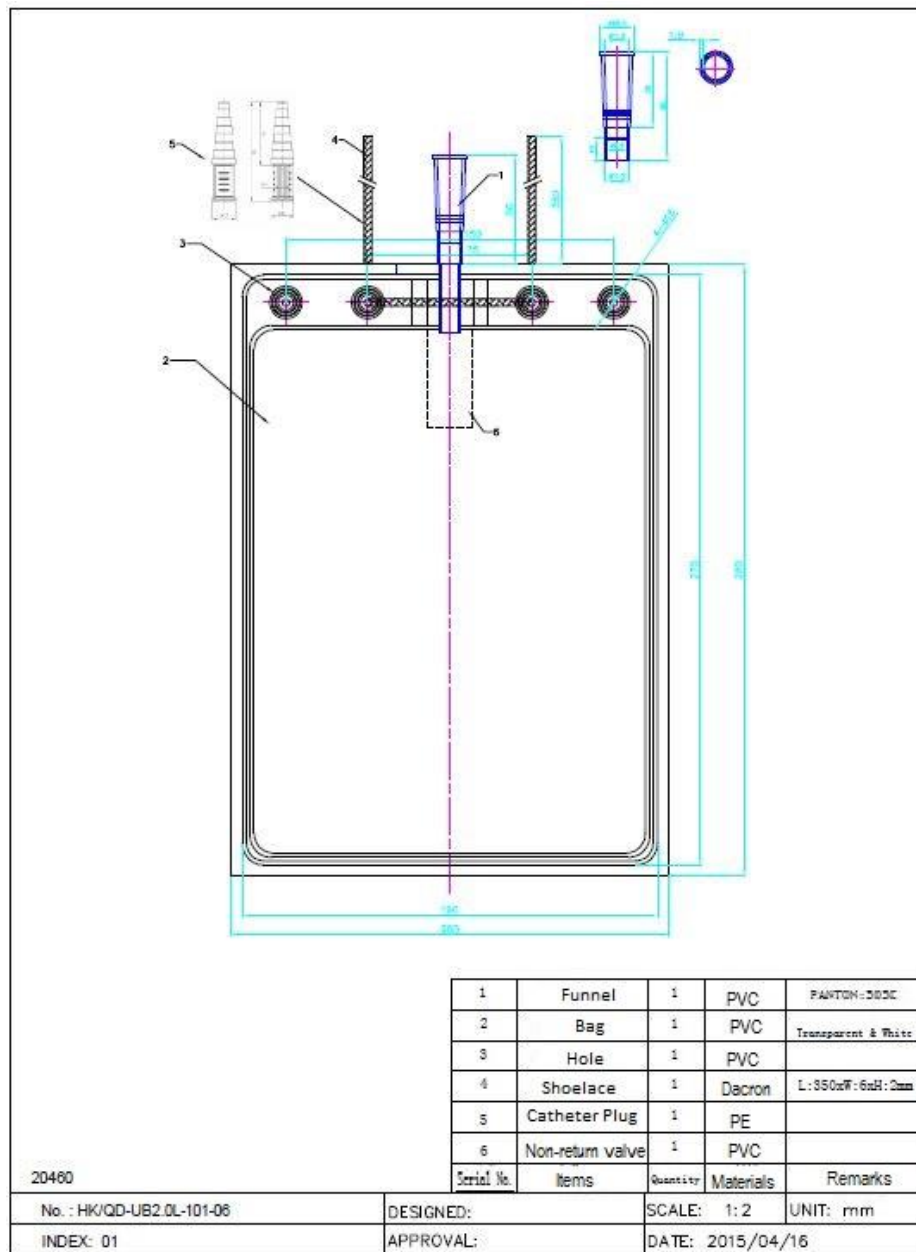
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Proposed Disposal Method

- The used C3 Emptying Bag can be disposed in either a Biohazard Bin, Cytotoxic Bin or a Regular Bin, depending on the nature of the collected waste.
- Dispose used product into clinical waste bag or according to clinical waste protocol, e.g., incineration, for contaminated waste.

Technical Drawing

REF 20460



Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

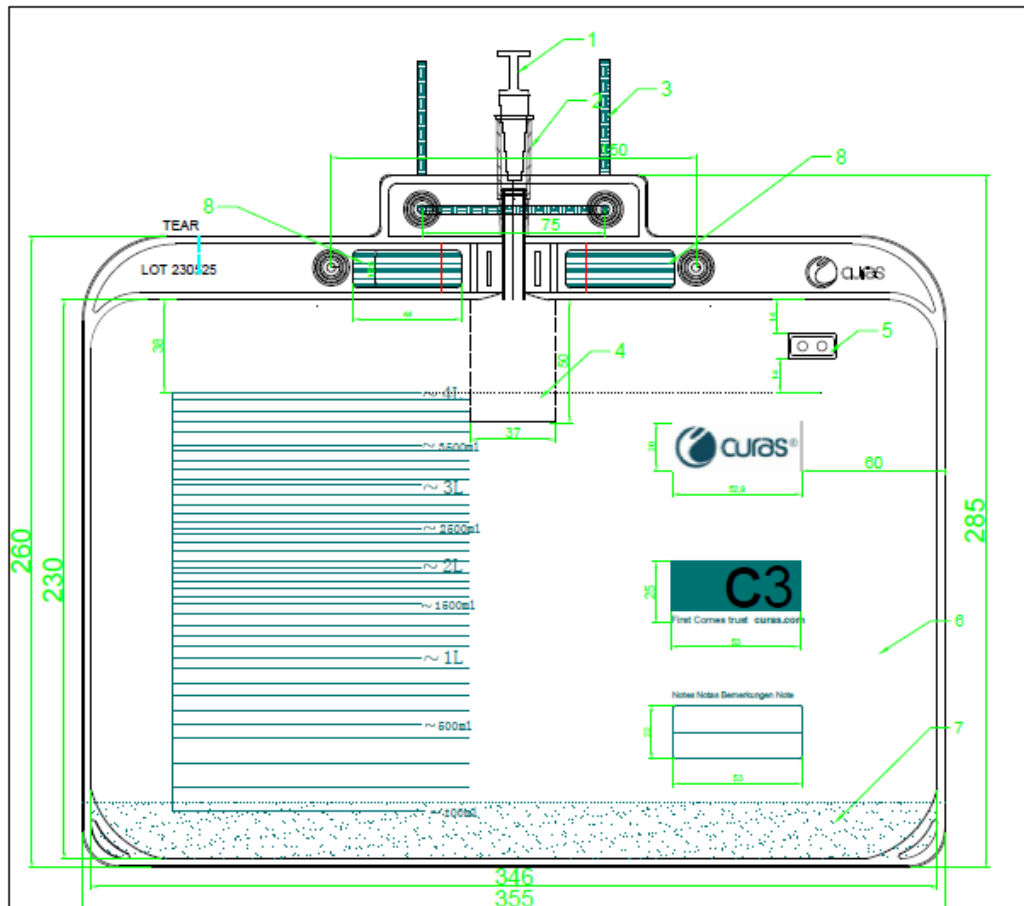
Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

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REF 20462



The thickness of bag body is 0.25mm on one side

REF 20462

8	plastic sheet		ABS	44*15.5*3mm
7	SAP	65g		
6	Bag	1	PVC	Transparent&White DEHP FREE
5	Filter	1	PA	5µm
4	NRV	1	PVC	DEHP FREE 37*50mm
3	Cross-hanger	1	Dacron	L:350mm; OD:3.7mm
2	Big Funnel	1	PVC	Pantone 303C DEHP FREE
1	Catheter spigot	1	pp	Pantone 303C
serial NO.	Items	quantity	material	Remarks

Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

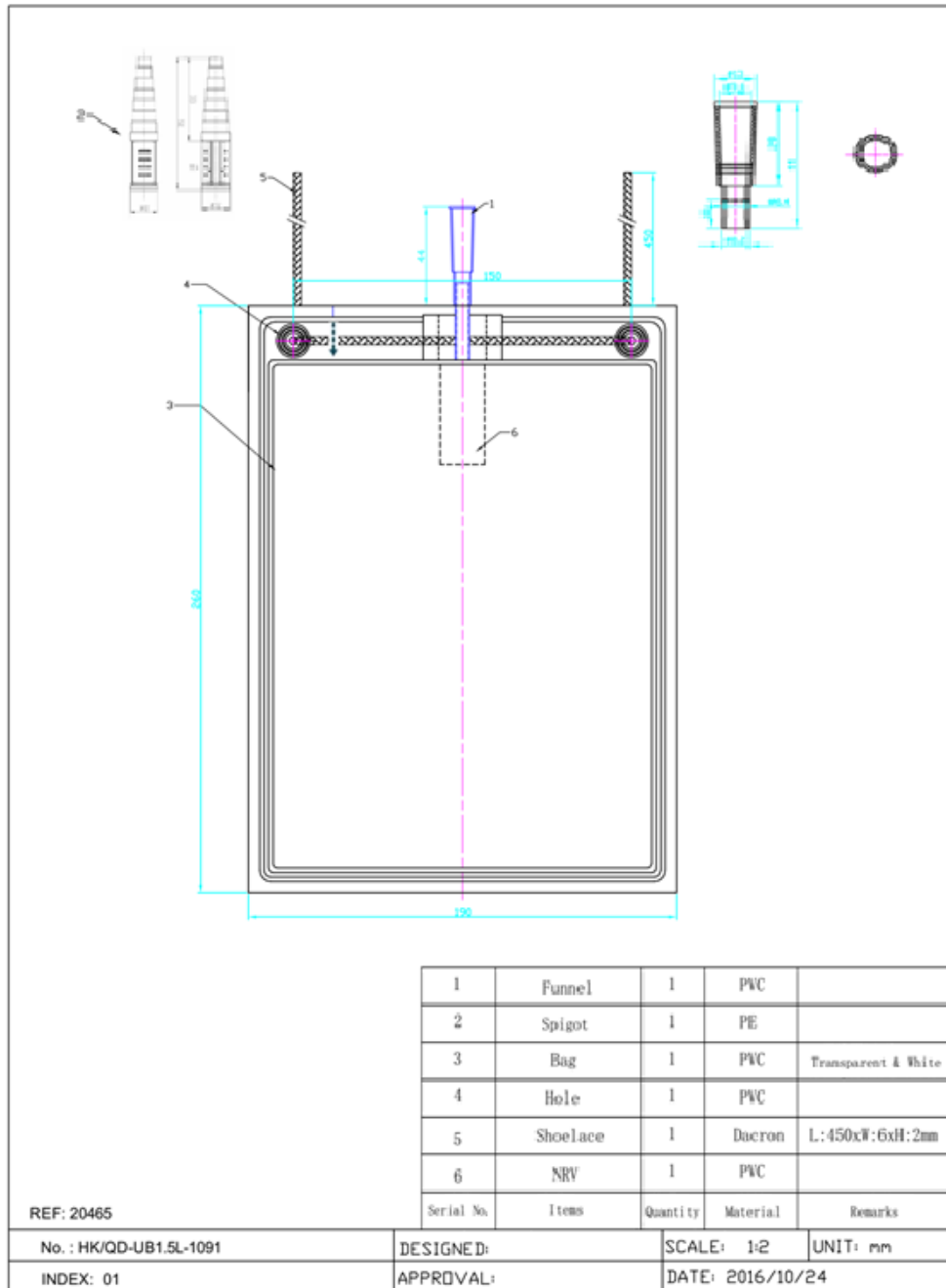
Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

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REF 20465



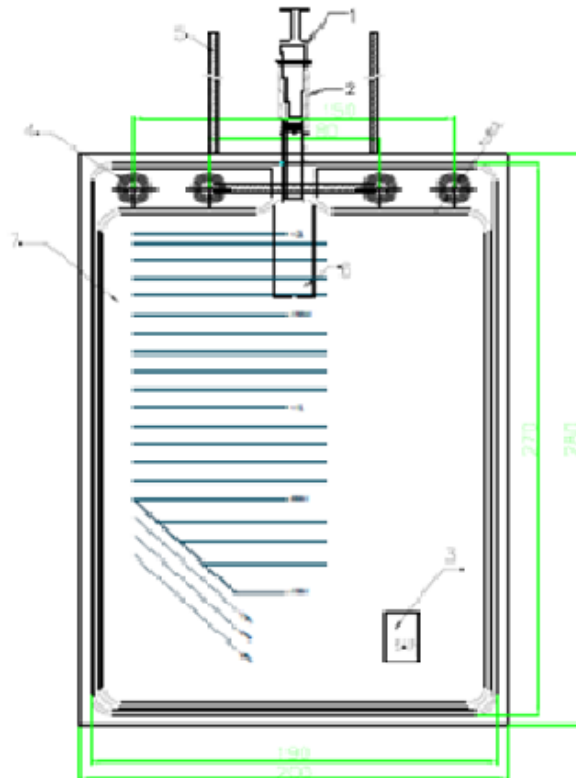
Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

TDS/2046X_2047X/C3WSAP/111024/03

REF 20469


Bag body single layer
thickness 0.115mm

REF: 20469

1	Catheter Spigot	1	PP	Pontone 303C
2	Small Funnel	1	PVC	Pontone 303C 300° F100
3	SAP	1		25g
4	Hole	4	PVC	300° F100
5	Shoelace	1	Dacron	L:150mm; CD:1.7mm
6	NRV	1	PVC	300° F100
7	Bag	1	PVC	300° F100
Serial no.	Items	QTY	Materials	Remarks
No. : HK/QD-UB2.0L-1020		DESIGNED:	SCALE: 1:1	UNIT: mm
INDEX: 01		APPROVAL:	DATE: 2023/5/6	

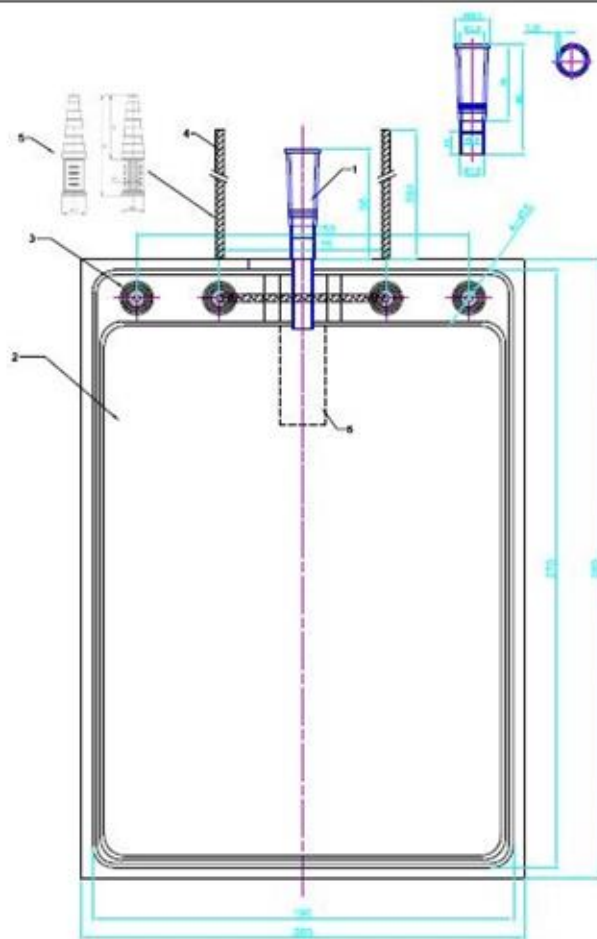
Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

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Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

20470

1	Funnel	1	PVC	PANTON-500C
2	Bag	1	PVC	Transparent & White
3	Hole	1	PVC	
4	Shoelace	1	Dacron	L:350mm; dia: 2mm
5	Catheter Plug	1	PE	
6	Non-return valve	1	PVC	
Serial No.	Items	Quantity	Materials	Remarks

No. : HK/QD-UB2.0L-101-06
DESIGNED:
SCALE: 1:2

UNIT: mm

INDEX: 01
APPROVAL:
DATE: 2015/04/16

TDS/2046X_2047X/C3WSAP/111024/03

Symbols

Emptying Bag Symbol



SAP by Curas™ Symbols



Inner Pouch Barcode (UDI)

- EAN-13 barcode and QR Code w/URL

REF 20460  5 051400 204609  www.curas.com/emptying-bags	REF 20462  5 051400 204623  www.curas.com/emptying-bags
REF 20465  5 051400 204654  www.curas.com/emptying-bags	REF 20469  5 051400 204692  www.curas.com/emptying-bags
REF 20470  5 051400 204708  www.curas.com/emptying-bags	

Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
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Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

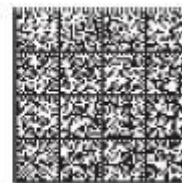
Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

Carton Barcode (UDI)

- GS1-128 barcode and Complex Data Matrix

REF 20460



REF 20462



(01)05051400204623(17)XXXXXX



(11)XXXXXX(10)XXXXXX(30)0160



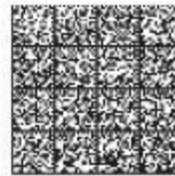
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(11)XXXXXX(10)XXXXXX(30)0200



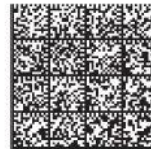
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(11)XXXXXX(10)XXXXXX(30)0150



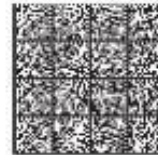
REF 20470



(01)05051400204708(17)260315



(11)210401(10)210401(30)0150



Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

Example of PE Bag Artwork



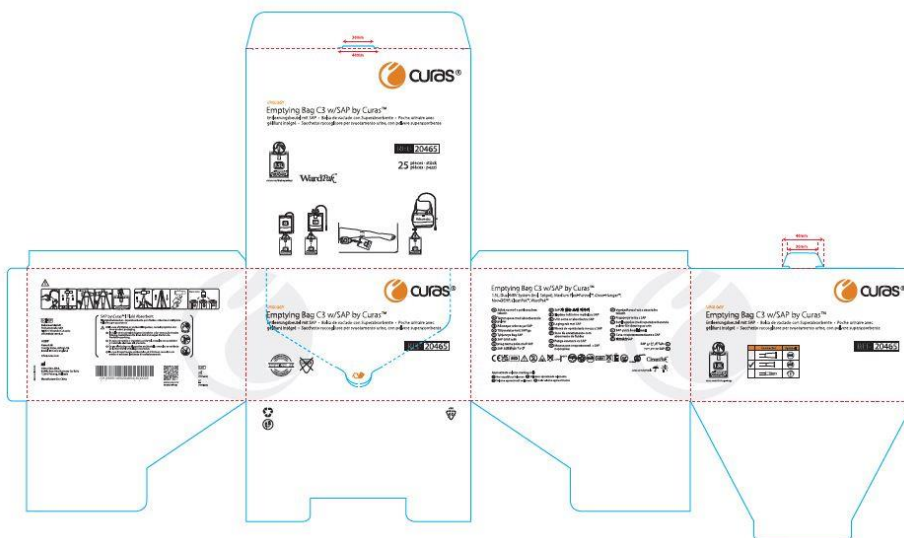
Example of Inner Box Artwork

Europe
Curas Ltd.
County Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

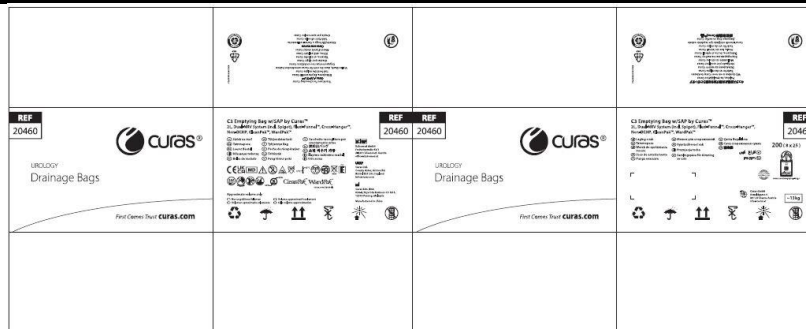
Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

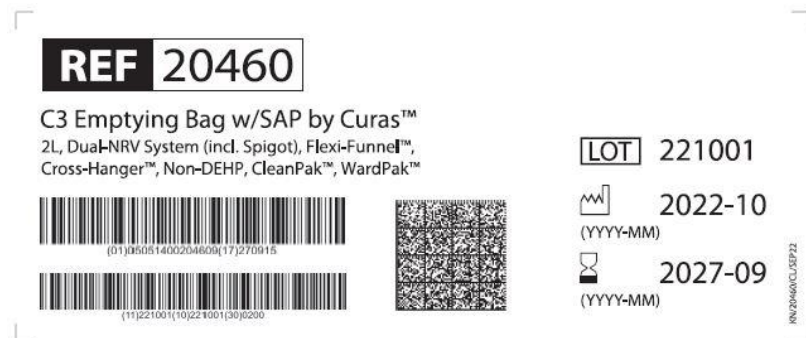
Worldwide
info@curas.com
www.curas.com



Example of Carton Artwork



Example of Carton Label Artwork



Europe
Curas Ltd.
Country Gates, Ashton Rd.
Bristol BS3 2JH
England
Phone +44 7796 338 585

Asia Pacific
69A-B Raja Uda Business
Centre Road 4, 12300
Penang, Malaysia

Phone +60 4 314 0525
Fax +60 4 314 0625

Worldwide
info@curas.com
www.curas.com

HS Code	: 3926909790
Manufacturer	: Curas Sdn. Bhd. 69A-B Raja Uda Business Ctr Rd 4 12300 Penang, Malaysia info@curas.com
EC Rep	: Kabomed GmbH Freiheitsstraße 43/1 A-2331 Vösendorf, Austria office@kabomed.at
UKRP	: Curas Ltd. Country Gates, Ashton Rd. Bristol BS3 2JH, England info@curas.com
Importer	: Curas GmbH Oswaldgasse 6 A-1120 Vienna, Austria info@curas.at