

adaptiQ®

SCHOTT Vials Ready To Use

Product Specification

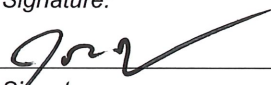
Type: adaptiQ® - SCHOTT Vials Ready to Use Cup Nest , material Fiolax® Clear - TopLine, Crimp Neck, size 6R NBB

Manufacturing Site:

SCHOTT North America Inc., Lebanon Valley Parkway 30, Lebanon, PA 17042, USA

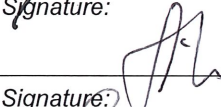
Article-No.	1762549
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Created by:
Johnson Dong
Technical Customer Support

Signature:


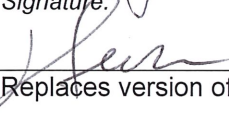
Date:
01-24-2021

Reviewed by:
Andreas Holstein
Operations Manager

Signature:


Date:
01-20-2021

Approved by:
Heather Shellenberger
Site Quality Manager

Signature:


Date:
01-28-2021

Created: 01-04-2021

Replaces version of:

00

Approval of Customer

Company Stamp:

Signature:

Date:



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CONFIDENTIAL! ONLY FOR DESIGNATED CUSTOMER!

This technical product information shall give the most important technical features of the adaptiQ® vial type mentioned above. Further technical details are always available on request. In any case, only the corresponding specifications released by our quality management are valid.

1. Scope

This documentation applies to adaptiQ® - SCHOTT Vials Ready To Use, TopLine.

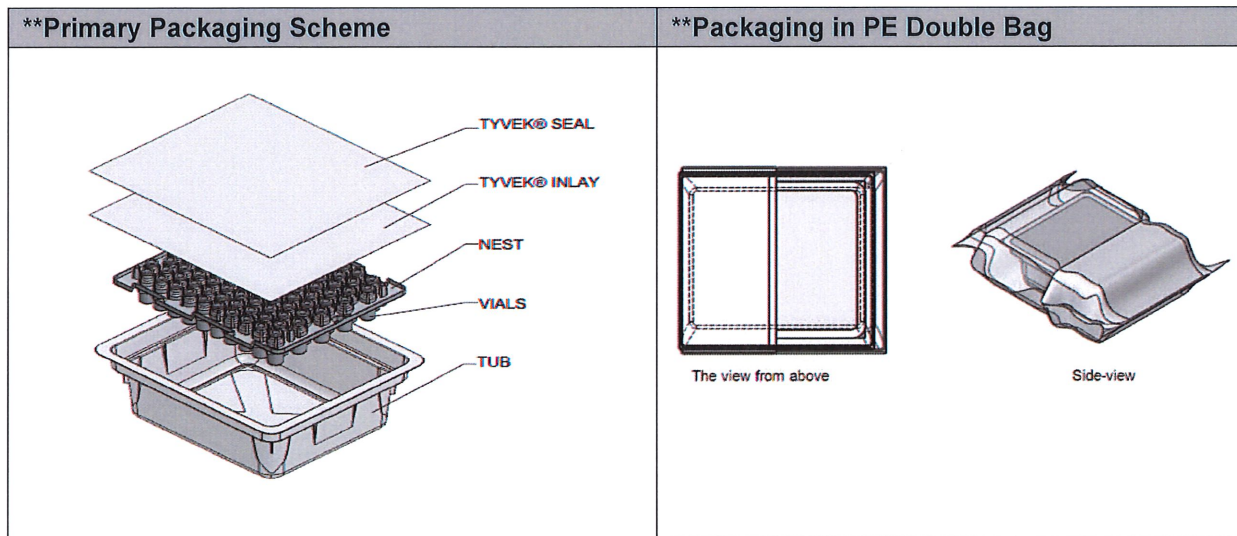
adaptiQ® represents a single use, sterile and non-pyrogenic glass vial for packaging parenteral medicinal products specifically designed to deliver reliable performance on our customers filling line.

The filling and closure of the vial is not completed by SCHOTT and is not SCHOTT's responsibility.

2. adaptiQ® vial - Product Description

Component	Material Description	Regulatory Reference
Glass vial (TopLine quality)	SCHOTT Fiolax® clear: <ul style="list-style-type: none"> ▪ Highly resistant borosilicate tubing glass (Type I) transparent ▪ First hydrolytic class according to the current version of EP, USP and JP 	<ul style="list-style-type: none"> ▪ Glass Container: USP 660*; EP 3.2.1*; JP 7.01*
Packaging materials**	<ul style="list-style-type: none"> ▪ Nest: Polyoxymethylene (POM), DELRIN SC690 NC010 ▪ Tub: Polystyrene (PS), N96 ▪ Single Tyvek® inlay ▪ Tub Seal: Tyvek® seal ▪ Double Bag: Low Density Polyethylene (LDPE)/Polyethylene terephthalate (PET) with Tyvek® ▪ Transport box: Akylux® 	<ul style="list-style-type: none"> ▪ Polymers according to USP <88> class VI*
Sterilization	<ul style="list-style-type: none"> ▪ ETO Sterilization 	<ul style="list-style-type: none"> ▪ ISO 11135* ▪ CPMP/QWP/159/01

*Current version



3. adaptiQ® vial - Packaging, Labelling, Storage

To protect the vials against contamination and damage the vials are placed in nests and the nests are placed in tubs.

The protective Tyvek® inlay and Tyvek® seal build a barrier against microbial contamination (sterile barrier). The LDPE bag acts as a protection against external contamination or damage. Additional plastic layers are put on top and bottom of the box as well as between each layer of tubs.

Packaging shall be checked prior to use for the presence of holes, tears, damaged or separated seal, which could affect the product sterility.

Packaging identification may include the following information:

	Tub / PE Bag	Box	Pallet
Supplier Name	X	X	X
Customer Name	-	-	X
Product Description	X	X	X
Article no.	X	X	X
Batch no.	X	X	X
No. of packaging	X	X	X
Quantity	X	X	X
Manufacturing Date	X	X	X
Expiry Date	-	X	-
Type of sterilization	-	-	X
User notices	X	X	-

User notices:

- Non toxic
- Non pyrogenic
- Single use
- Sterile when packaging is closed and undamaged
- User is responsible for compatibility with drug

SCHOTT recommends following good manufacturing practices in packaging, storage and handling of sterile adaptiQ® vials:

- Long term storage (more than 60 days) temperature range is defined within (> 15 °C and < 30°C / > 59°F and <86°F)
- During transport it is allowed to deviate from this requirement
- Storage shall be always above the dew point
- Longer term storage with exposure to sun light is not allowed
- The goods shall be stored in normal warehouse environment (no contaminants in the atmosphere) with pest control in place
- Shelf life is documented per Certificate of Conformity (CoC)
- Minimizing mechanical stress

The adaptiQ® vial is dedicated to be filled with drugs under aseptic conditions. It is the customer's responsibility to use the adaptiQ® vial in a correct way and to verify the stability of the filled drugs.

4. Product Conformity

With each batch SCHOTT provides a certificate of conformity (CoC) or a copy CoC in case of partial batch shipments.

The certificate is dated and signed (manually or electronically) by a quality assurance representative.

The adaptiQ® vials and packaging conform to the associated drawings, as released by both parties.

The customer is responsible to validate the vials as appropriate to their own process and use and must make sure that no further manufacturing or transportation steps affect the essential qualities of the vials.

5. Quality Assurance

The quality system at SCHOTT is defined in the Quality Manual and related procedures. SCHOTT's Quality system is certified under:

- ISO 9001 current version
- ISO 15378 current version

The SCHOTT glass vials made of Type I borosilicate glass fulfil the requirements of the following Pharmacopeia:

- Ph. Eur, chapter 3.2.1
- USP, chapter 660
- JP, chapter 7.01

General

- Converting line with online dimensional control
- Visual defects checked by Automated Inspection Systems and statistical in-process control
- Packaging in controlled area

Batch Definition / Customer Samples

A unique 10 digit batch number is used for numbering each batch of the product. The batch number begins with a 6-.

Sampling of SCHOTT adaptiQ® sterile is representative for the total batch produced. Tailgate samples could be supplied on request and are applicable only if a full production batch is delivered. The tailgate samples will be placed in separate box(es) and labelled „Customer Samples“ and the box(es) are included in the palletization configuration of the last pallet.

The sample size is based on a Single Sampling Plan as defined in ISO 2859-1 / ANSI / ASQ Z1.4 Level II.

Quality Level

SCHOTT is committed to supply a product that meets the following acceptable quality level (AQL) according to ISO 2859-1. / ANSI Z1.4.

For the cosmetic defect inspection level II is taken, for all other inspection, e.g. dimensional defects, inspection level –S4 is used.

Note: If with respect to a certain type of defect the applicable AQL is maintained at the moment of incoming inspection in accordance with the procedures of ISO 2859-1 / ANSI Z1.4, all pieces of the relevant batch shall - with regard to that type of defect - be deemed in compliance with the Specifications.

AQL Table by category

Packaging

No.	Defect / Specification	Defect Class.	Defect definition	AQL
I	Product mix-up	C	-	None allowed **
II	Wrong or missing printing or labeling on tub	M (A)	-	0.015
III	Missing inner Tyvek®	M (A)	-	0.015
IV	Missing vial in nest	M (A)	-	0.1
V	Incomplete seal on tub	M (A)	-	0.065
VI	Incorrectly positioned Tyvek®	M (A)	-	0.1

Dimensional – Listed defects per dimensions on Product Drawing

No.	Defect/ Specification	Defect Class	Reference dimension only	AQL
10.01.0	Total height (overall length) out of tolerance	M (A)	Reference: Drawing size h1	0.25
10.03.0	Outer body diameter out of tolerance	M (A)	Reference: Drawing size d1	0.25
10.09.0	Neck outer diameter out of tolerance	M (A)	Reference: Drawing size d3	0.25
10.14.0	Flange (collar) outside diameter out of tolerance	M (A)	Reference: Drawing size d2	0.25
10.15.0	Flange (collar) height out of tolerance	M (A)	Reference: Drawing size h21	0.25
10.02.0	Body height out of tolerance	M (A)	Reference: Drawing size h2	0.4
10.05.0	Bottom thickness out of tolerance	M (A)	Reference: Drawing size s2	0.4
10.06.0	Bottom concavity out of tolerance	M (A)	Reference: Drawing size t	0.4
10.10.0	Neck inside diameter out of tolerance	M (A)	Reference: Drawing size d4	0.4
10.12.0	Perpendicularity out of tolerance	M (A)	Reference: Drawing size a	0.4
10.16.0	Lower flange (collar) angle out of tolerance	M (A)	Reference: Drawing size c21	0.4
10.19.0	Neck height out of tolerance	M (A)	Reference: Drawing size h3	0.4
10.04.0	Wall thickness out of tolerance	M (B)	Reference: Drawing size s1	1.0
10.13.0	Flange (collar) angle (top of flange) out of tolerance	N	Reference: Drawing size c22	4.0

Cosmetic

No.	Defect / Specification	Defect Class.	Defect definition	AQL
04.01.0	Inside contamination	C	Size > 0.3 mm ² , visible by naked eye	0.1
04.03.0	Outside contamination	N	Not removable, size > 0.5 mm ²	1.0
04.03.0	Contamination sealing surface (dirt)	M	Visible by naked eye, size > 0.3 mm ²	0.1
05.18.0	Glass particles inside vial	C	Size > 0.5 mm	None allowed *
05.17.0	Glass particles inside vial	C	Size > 0.2 to 0.5 mm	0.25
05.05.0	Deformed containers, processibility impaired	M (A)	Test according to Visual Inspection of limit samples	0.4
05.06.0	Deformed containers, processibility not impaired	N	Test according to Visual Inspection of limit samples	4.0
05.07.0	Cracks	C	Any size, penetrating the wall	None allowed *
05.10.0	Chips on body	C	Risk of leakage, size > 1 mm	None allowed *
05.08.2	Bump Checks	N	1 check > 0.5 mm or sum of several checks > 1 mm. Not penetrating the wall	1.0
05.09.0	Chips on collar	C	Clearly visible, with risk of leakage > 50% affected in one location of the vial, non-accumulative	None allowed *
05.09.0	Chips on collar	N	Clearly visible, no risk of leakage 25%-50% of surface affected in one location of the vial, non-accumulative	1.0
05.11.0	Folds or notches in shoulder, neck, collar	C	Sealing surface > 50% affected in one position	None allowed *
05.11.0	Folds or notches in shoulder, neck, collar	M	25% - 50% of sealing surface affected in one position	0.4
05.12.0	Folds or notches in shoulder, neck, collar	N	Sealing not affected, function not impaired, 1 notch > 0.5 mm width on collar side, several notches length > 2/3 of collar height and > 2/3 of circumference	4.0
05.14.0	Airlines	N	Closed airlines width > 0.1 mm and length > 4.0 mm	0.4
05.14.0	Airlines	M	Open airline at inside, width > 0.1 mm and length > 4.0 mm	0.04
05.15.0	Air bubbles	M	Diameter > 1 mm	0.1
05.15.0	Air bubbles	N	Diameter 0.5 to 1 mm	1.0
05.16.1 05.16.2	Inclusions (knots & stones)	M	Size > 1 mm	0.1
05.16.1 05.16.2	Inclusions (knots & stones)	N	Size 0.3 to 1 mm	1.0
05.19.0	Cooling stress out of tolerance	M (A)	Testing procedure according to TP no. RG 19.05/-	0.4
05.18.0	Glass threads inside	M	Length > 2mm and width > 0.3 mm	0.4
05.13.0	Scratches	N	- 1 scratch width > 0.2 mm and length > 20 mm - 2 or more scratches width > 0.2 mm and sum of length > 40 mm - 1 radial scratch width > 0.2mm and > 1/2 of circumference	4.0
05.50.0	Tools marks (scars) in shoulder or neck	N	Marks and scars which are clearly visible by naked eye	2.5
05.51.0	Pressure marks on neck	M	Ring shape, near neck and shoulder, visible by naked eye	0.25
05.51.0	Pressure marks on neck	N	Spiral shape or vertical, length of > 1/2 neck height and > 1/2 circumference	1.0
05.50.0	Tool marks on bottom	N	Grooves and notches > 3 mm or rough surface or rings with a width > 2 mm or tool marks clearly visible from top through opening. Function impaired.	1.0
06.07.0	Wavy bottom	M (A)	High and low areas where the side wall meets the bottom resulting in an incomplete footprint and not usable	0.1

Chemical/Biological/Particulate Specifications

Item	Test	Defect Class.if failure	Specification Limit	AQL
A	Endotoxin	C	< 0.25 EU / ml	None allowed
B	Residual ETO	C	< 1 µg / ml	None allowed
C	Residual ECH	C	< 50 µg / ml	None allowed
D	Subvisible particles Particle count ≥ 10 µm	M	< 600 Particles / container (10% USP 788)	0.1
E	Subvisible particles Particle count ≥ 25 µm	M	< 60 Particles / container (10% USP 788)	0.1

*50 ppm allowed in lot.
**in the delivery

C = FBL* Defect Class 1= Critical Defect. Critical defects are those whose presence can have critical consequences.
M = FBL Defect Class 2 = Major Defect. Major defects are defects whose presence can lead to considerable impairments.
M (A) = Usability of packaging material markedly impaired.
M (B) = Usability of packaging material moderately impaired.
N = FBL defect Class 3 = Minor Defect. Minor defects are defects whose presence does not have essential consequences, e.g. they represent a reduction in general quality.
* FBL: Defect Evaluation List (DEL), 2009

Notes:

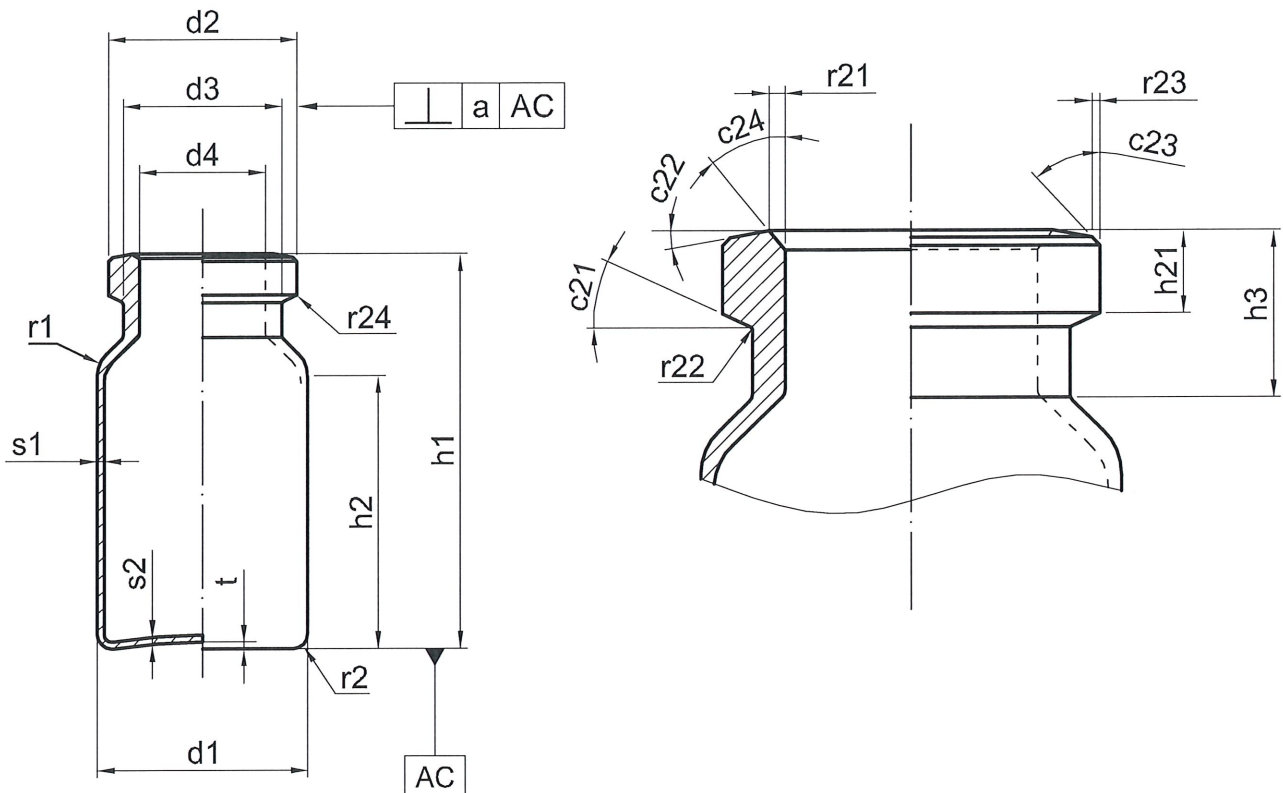
- Schott's defect manual lists a number of additional, potential cosmetic glass imperfections, these are classified as Acceptable Cosmetic Imperfections (ACI), unless otherwise stated.
- Cosmetic defects are verified under Standard inspection conditions: as defined in USP <790>
- Dimensions are non API, unless otherwise specified
- All defects are non-cumulative.

6. History

Version	Date of change	Description of change
00	09-24-2019	Initial Development version
01	01-04-2021	Release FHU via CR-00165

7. Drawings

Annex 1 / 10000003405 / 6R NBB.....	9
Annex 2 / 2233285-01 / 6R Cup-Nest.....	10
Annex 3 / 223795-14 / Tub N96 white.....	11
Annex 4 / 1293687-00 / Drawing packaging configuration	12

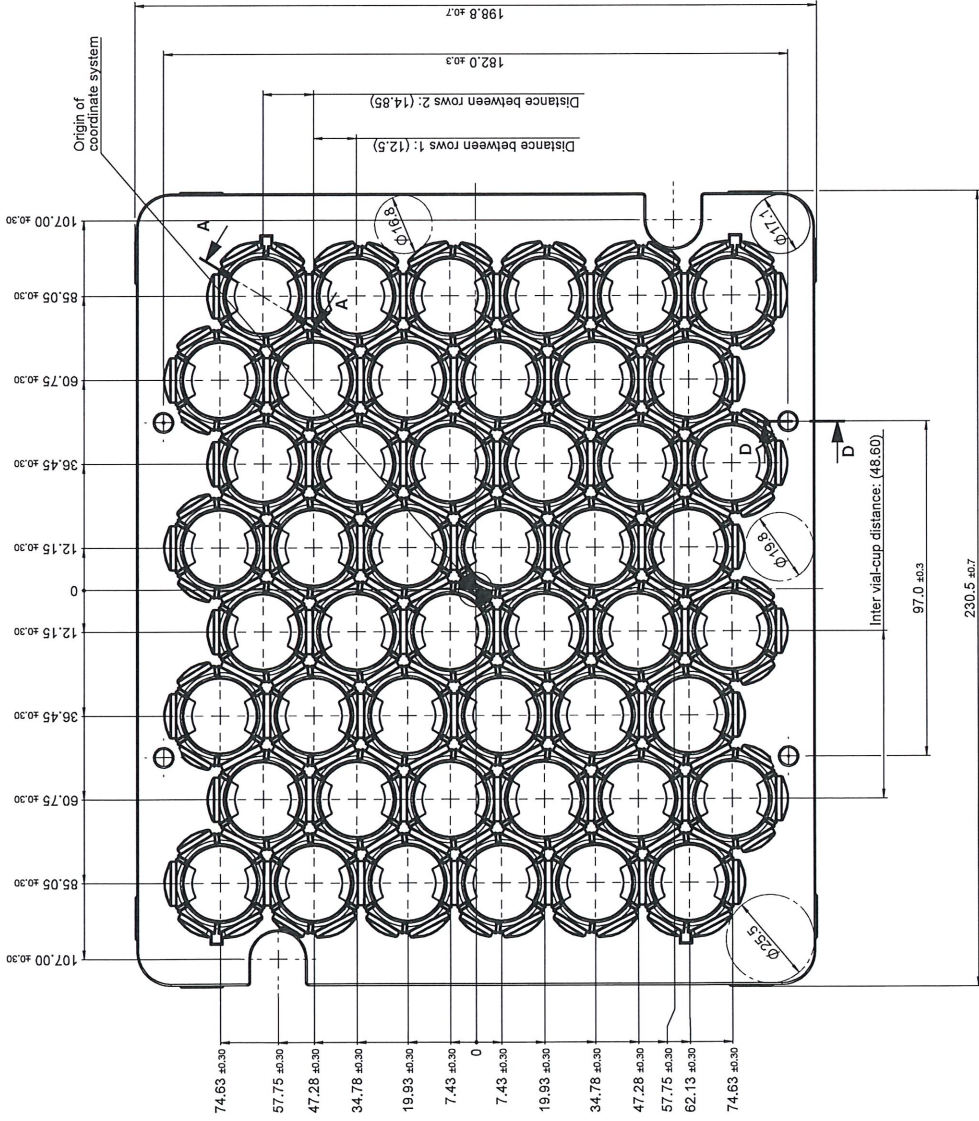
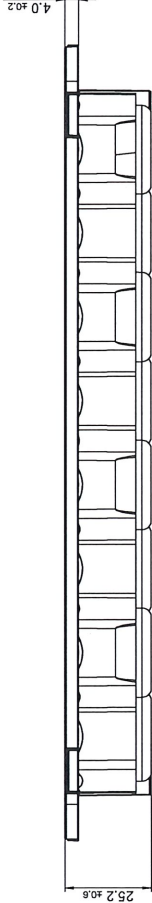


d1	22,0	+ 0,2	-0,2	c21°	10,0	+ 5,0	-5,0	r21	0,5	ca.	
d2	20,0	+ 0,2	-0,3	c22°	3,0	+ 2,0	-2,0	r22	0,5	ca.	
d3	16,5	max.		c23°	45,0	ca.		r23	0,5	ca.	
d4	12,6	+ 0,2	-0,2	c24°	45,0	ca.		r24	0,5	ca.	
h1	40,0	+ 0,5	-0,5	s1	1,0	+ 0,04	-0,04	t	0,7	max.	
h2	26,0	min.		s2	0,7	min.		a	1,2		
h3	8,5	+ 0,5	-0,5	r1	3,5	ca.					
h21	3,6	+ 0,2	-0,2	r2	2,0	ca.					

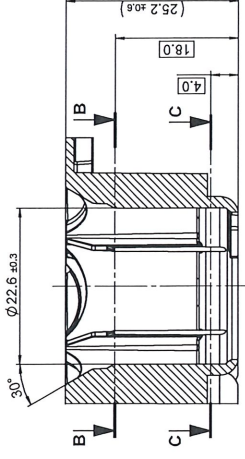
Modification	Previously	New	Date	Vers.

Description: Vial ISO 8362-1 6R-1		Creator: Bálint Szabados		Product drawing SCHOTT forma vitrum
Drawing Number: 1000003405		Approved: Lajos Pungor		
		Status: RD	15.01.2010	
Drawing ID: 1000003405-000/00				NOTE: Linear dimensions are in millimeter

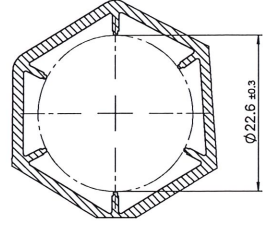
Tolerance group	1 - 3	> 3 - 6	> 6 - 10	> 10 - 18	> 18 - 30	> 30 - 50	> 50 - 80	> 80 - 120	> 120 - 180	> 180 - 250
TG6	±0.07	±0.12	±0.18	±0.22	±0.26	±0.31	±0.37	±0.45	±0.57	±0.80
NW	±0.12	±0.18	±0.22	±0.26	±0.31	±0.37	±0.45	±0.57	±0.80	±1.05



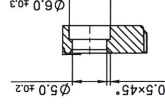
A-A (2 : 1)



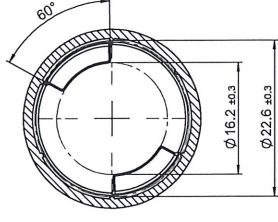
B-B (2 : 1)



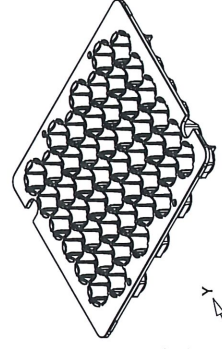
D-D (2 : 1)



C-C (2 : 1)



(1 : 3)



The component is rotationally symmetric

ID	DCR/0172	2019-03-01	01	1993-03-08	2020-08-14	IND. CHANGE	DATE	IND. CHANGE	DATE	IND. CHANGE	DATE	IND. CHANGE	DATE
STATUS	NO	DATE	NAME	NOTE	GENERAL TOLERANCE	FILE	DATE	IND. CHANGE <td>DATE <td>IND. CHANGE <td>DATE <td>IND. CHANGE <td>DATE </td></td></td></td></td>	DATE <td>IND. CHANGE <td>DATE <td>IND. CHANGE <td>DATE </td></td></td></td>	IND. CHANGE <td>DATE <td>IND. CHANGE <td>DATE </td></td></td>	DATE <td>IND. CHANGE <td>DATE </td></td>	IND. CHANGE <td>DATE </td>	DATE
CREATED	2020-08-14	Marcus Müller	DA: 18742 - 105	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285
APPROVED	2020-08-14	David Hübner	DA: 18742 - 105	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285
RELEASED	2020-08-14	Christoph Friedrich Schulze	DA: 18742 - 105	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285	2233285

DESCRIPTION
Cup-Nest 6R 48 Ø22.6 mm

PG: NIST POM 231X198X25 NA 48 22.6

DRAWING NUMBER: 2233285

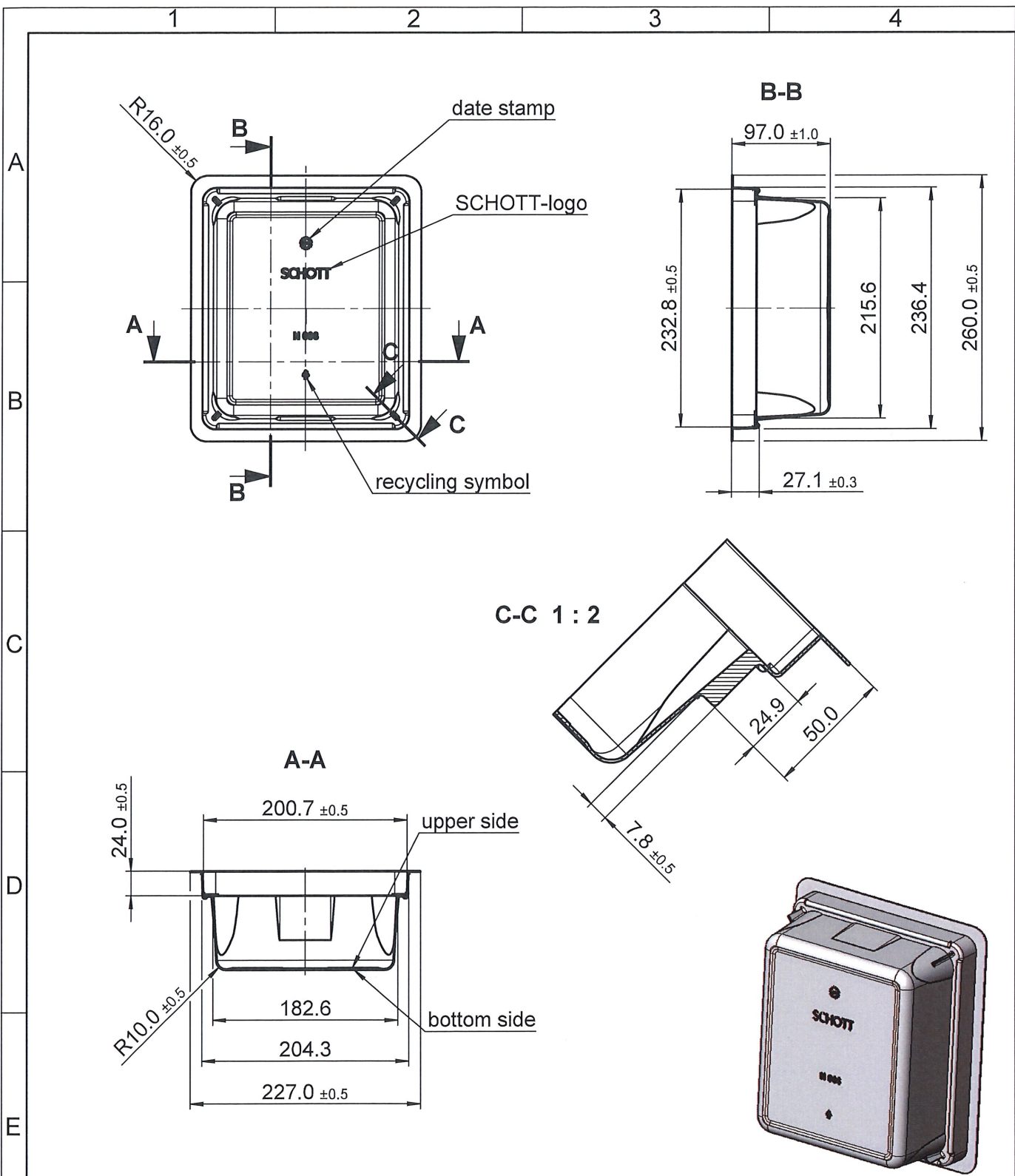
INDEX: 01

MATERIAL: POM

PAGE: 1/1

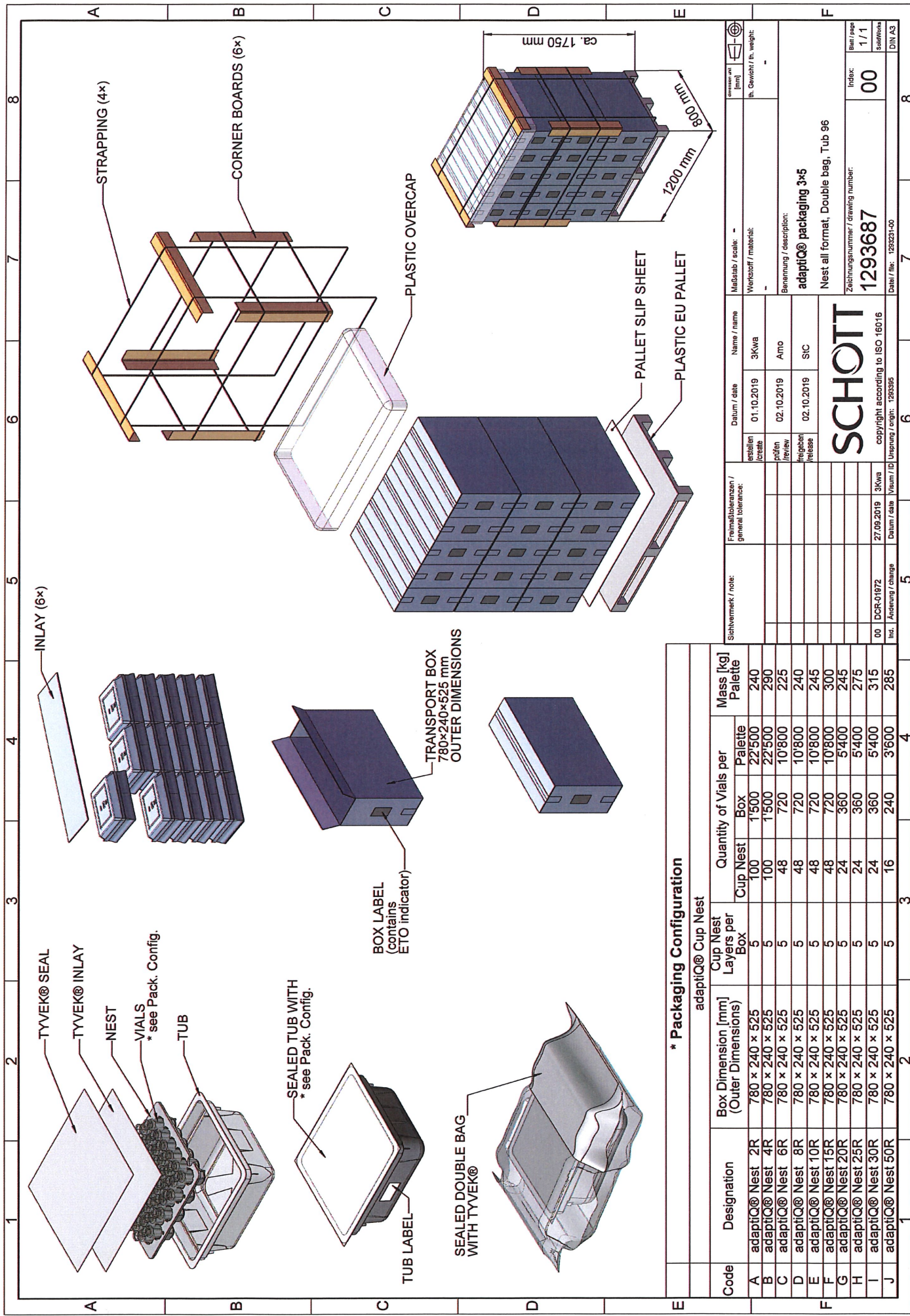
SCHOTT

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Sichtvermerk / note:		Freimaßtoleranzen / general tolerance:		Datum / date		Name / name		Maßstab / scale: 1:5 (1:2)		dimension unit: [mm]			
		DIN 16901 - 130		erstellen / create		13.01.2015 StC		Werkstoff / material:		th. Gewicht / th. weight: [g]		156.81	
				prüfen / review		13.01.2015 Gin		PS					
				freigeben / release		13.01.2015 Fis		Benennung / description:					
14 DCR-00712		13.01.2015 StC						Tub N96 white					
13 DCR-00643		29.09.2014 StC						SYG PG TUB 096 WHI					
12 DCR-00632		23.09.2014 Kma						Zeichnungsnummer / drawing number:		Index:		Blatt / page	
11 DCR-00592		01.07.2014 Kma						223795		14		1 / 1	
10 DCR-00575		18.06.2014 Kma								SolidWorks		DIN A4	
Ind. Änderung / change		Datum / date		Visum / ID		Ursprung / origin:		Datei / file: 223795-13		Model Index: 14			

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*** Packaging Configuration**

Code	Designation	Box Dimension [mm] (Outer Dimensions)	Cup Nest Layers per Box		Quantity of Vials per Palette		Mass [kg] Palette
			Cup Nest	Box	Cup Nest	Palette	
A	adaptiQ® Nest 2R	780 x 240 x 525	5	1'500	22'500	240	
B	adaptiQ® Nest 4R	780 x 240 x 525	5	1'500	22'500	290	
C	adaptiQ® Nest 6R	780 x 240 x 525	5	48	10'800	225	
D	adaptiQ® Nest 8R	780 x 240 x 525	5	48	10'800	240	
E	adaptiQ® Nest 10R	780 x 240 x 525	5	48	10'800	245	
F	adaptiQ® Nest 15R	780 x 240 x 525	5	48	10'800	300	
G	adaptiQ® Nest 20R	780 x 240 x 525	5	24	5'400	245	
H	adaptiQ® Nest 25R	780 x 240 x 525	5	24	5'400	275	
I	adaptiQ® Nest 30R	780 x 240 x 525	5	24	5'400	315	
J	adaptiQ® Nest 50R	780 x 240 x 525	5	16	3'600	285	

adaptiQ® Cup Nest

Stellen / slots	Datum / date	Name / name	Maßstab / scale
stellen / slots	01.10.2019	3Kwa	Verstärkt / material
prüfen / review	02.10.2019	Amo	
freigegeben / release	02.10.2019	SIC	

Präzisionsbereich / general tolerance	Datum / date	Version / ID	Ursprung / origin
	27.05.2019	3Kwa	
			copyright according to ISO 16016
			Ursprung / origin: 1293395

Sichtvermerk / note	Datum / date	Version / ID	Ursprung / origin
00	DCR-01972	3Kwa	
			Ursprung / origin: 1293395

Benennung / description	Zeichnungsnummer / drawing number	Blatt / page
adaptiQ® packaging 3x5	Nest all format, Double bag, Tub 96	1 / 1
	12933687	00

Index	Scale	DIN A3
00	1 / 1	

Stellen / slots	Datum / date	Name / name	Maßstab / scale
stellen / slots	01.10.2019	3Kwa	Verstärkt / material
prüfen / review	02.10.2019	Amo	
freigegeben / release	02.10.2019	SIC	

Benennung / description	Zeichnungsnummer / drawing number	Blatt / page
adaptiQ® packaging 3x5	Nest all format, Double bag, Tub 96	1 / 1
	12933687	00

Index	Scale	DIN A3
00	1 / 1	