

adaptiQ®

# SCHOTT Vials Ready to Use

Product specification

Type: adaptiQ® SCHOTT Vials Ready to Use, Cup, Fiolax® Clear, TopLine, Crimp Neck, size 2R NBB

**Manufacturing Site:**

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

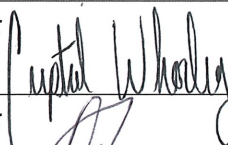
**Article-No.**

**1761533**

**Created by:**

Crystal Whorley  
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Signature:




Date:

21-Dec-2020

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Signature:



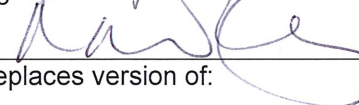
Date:

12-28-2020

**Approved by:**

Anthony Perry  
Regional Quality Manager

Signature:



Date:

05-JAN-2021

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Replaces version of:

00

**Approval of Customer**

Company Stamp:

Signature:

Date:

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*\*\*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® vials.

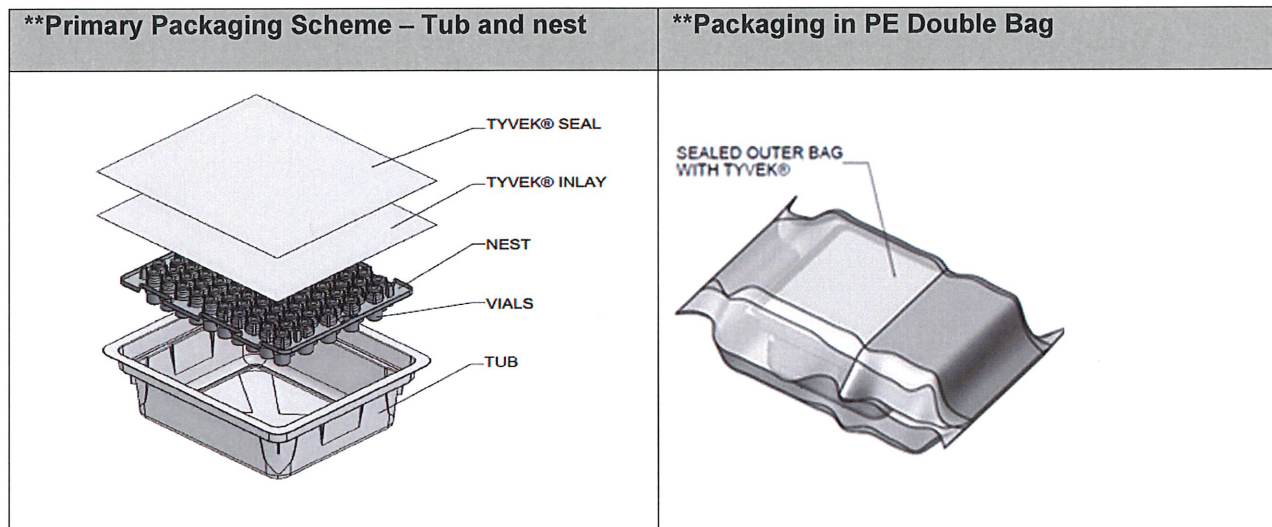
adaptiQ® represents a single use, sterile and non-pyrogenic glass vial for packaging parenteral medicinal products specifically designed to deliver reliable performance on filling lines.

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
<b>Tubing/ Vial</b>	SCHOTT FIOLAX® clear: <ul style="list-style-type: none"> <li>Highly resistant borosilicate tubing glass (Type I) transparent</li> <li>First hydrolytic class according to EP, USP and JP in its current version</li> <li>Supplier: SCHOTT AG, Business Unit Tubing</li> </ul>	<ul style="list-style-type: none"> <li>Glass Container: USP 660*; EP 3.2.1*; JP 7.01*</li> </ul>
<b>Packaging materials (Tub and nest configuration)**</b>	<ul style="list-style-type: none"> <li>Nest: Polyoxymethylene (POM), DELRIN SC690 NC010</li> <li>Nest Design: Cup</li> <li>Tub: Polystyrene (PS), N96</li> <li>Single Tyvek® inlay</li> <li>Tub Seal: Tyvek® seal</li> <li>Double Bag: Low Density Polyethylene (LDPE)/Polyethylene terephthalate (PET) with Tyvek®</li> <li>Transport box: Akylux®</li> </ul>	<ul style="list-style-type: none"> <li>Polymers according to USP &lt;88&gt; class VI*</li> </ul>
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>ETO Sterilization</li> </ul>	<ul style="list-style-type: none"> <li>ISO 11135*</li> <li>CPMP/QW P/159/01</li> </ul>

\* Current version



## 3. 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 placed 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® vials are dedicated to be filled with drugs under aseptic conditions. It is the customer's responsibility to use the adaptiQ® vials 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 and if required a certificate of analysis (CoA). 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 by TUEV Rheinland Cert GmbH, Cologne, Germany (accredited by DAkkS: D-ZM-16031-01-00) against:

- 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 batch number is used for numbering each batch of the product.

Sampling of adaptiQ® is representative for the total batch produced. Tailgate samples could be supplied on request and are applicable only if a full batch is delivered: The tailgate samples will preferably be placed in separated boxes marked with an appropriate label. Individual configuration for customer samples upon customer request.

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

### 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 <sup>2</sup> , visible by naked eye	0.1
04.03.0	Outside contamination	N	Not removable, size > 0.5 mm <sup>2</sup>	1.0
04.03.0	Contamination sealing surface (dirt)	M	Visible by naked eye, size > 0.3 mm <sup>2</sup>	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:

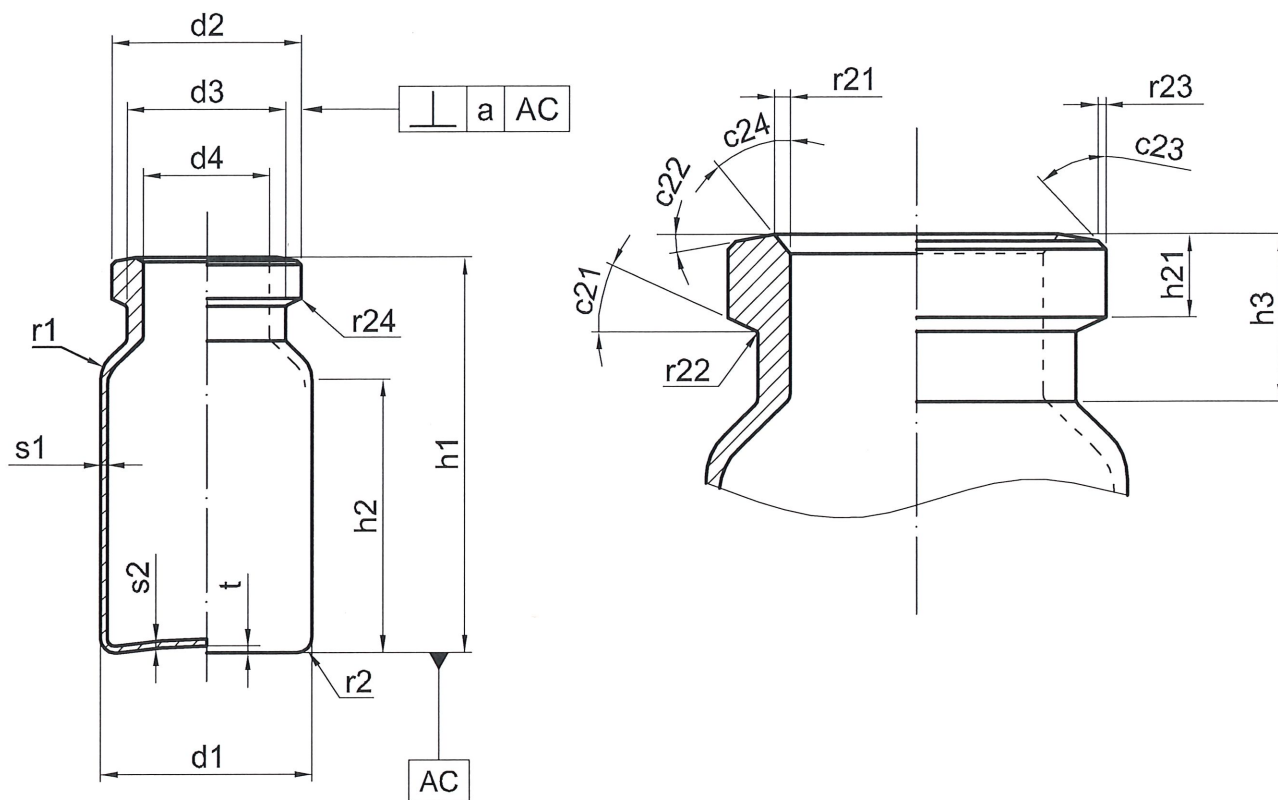
- Schott's defect manual lists a number of additional, potential cosmetic glass imperfections, these are classified as Acceptable Cosmetic Imperfections (ACI), unless otherwise stated.
- Cosmetic defects are verified under Standard inspection conditions: as defined in USP <790>
- Dimensions are non API,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

## 6. History

Version	Date of change	Description of change
00	10-12-2020	Release FHU via CR-00148
01	12-15-2020	Update Cup nest drawing from 2233284-00 to 2233284-01

## 7. Drawings

Annex 1 / 10000004995 / 2R NBB.....	9
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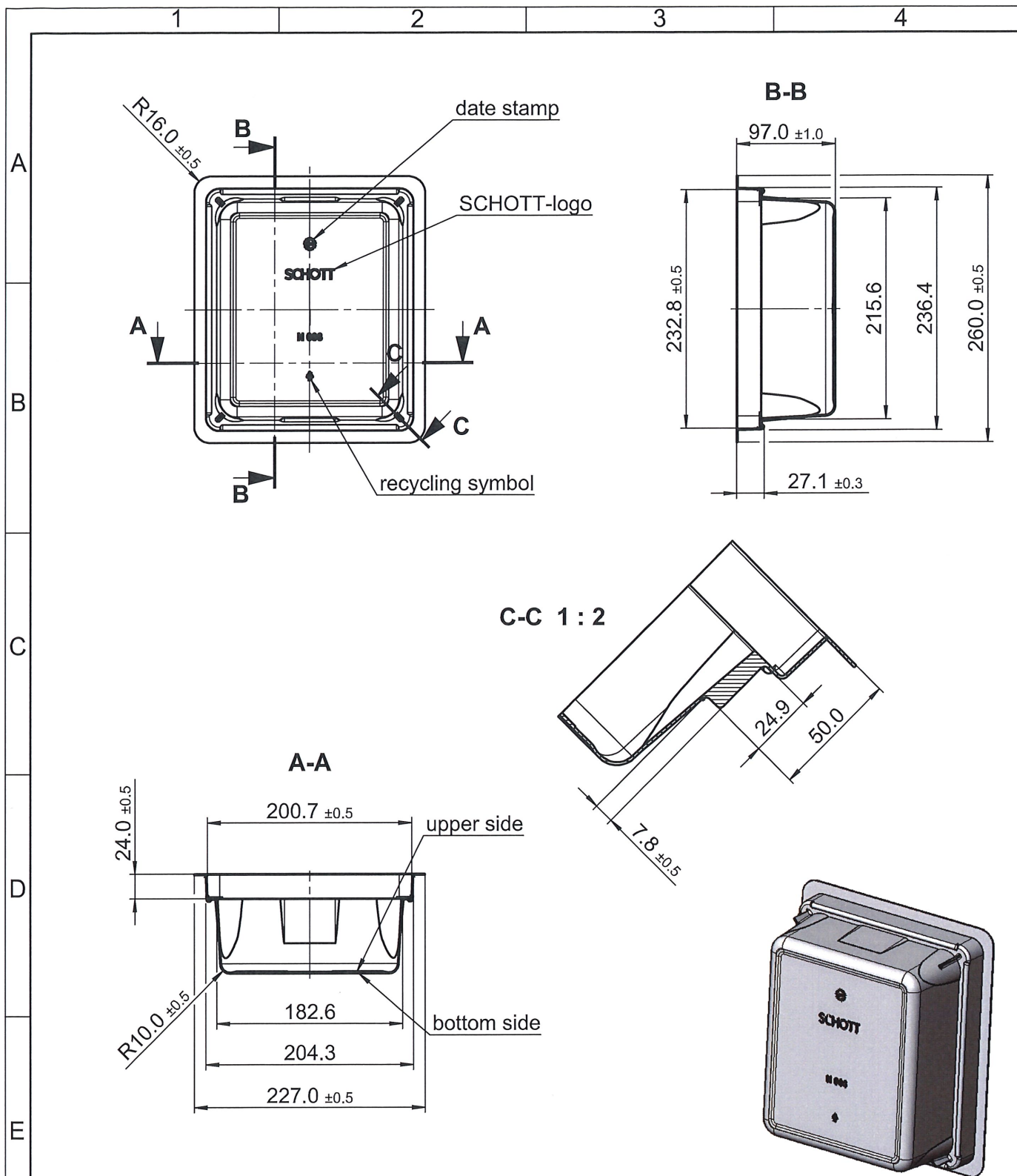


d1	16,0	+ 0,15	-0,15	c21°	10,0	+ 5,0	-5,0	r21	0,5	ca.	
d2	13,0	+ 0,2	-0,3	c22°	3,0	+ 2,0	-2,0	r22	0,5	ca.	
d3	10,5	max.		c23°	45,0	ca.		r23	0,5	ca.	
d4	7,0	+ 0,2	-0,2	c24°	45,0	ca.		r24	0,5	ca.	
h1	35,0	+ 0,5	-0,5	s1	1,0	+ 0,04	-0,04	t	0,7	max.	
h2	22,0	min.		s2	0,6	min.		a	1,0		
h3	8,0	+ 0,5	-0,5	r1	2,5	ca.					
h21	3,6	+ 0,2	-0,2	r2	1,5	ca.					

Modification	Previously	New	Date	Vers.

Description: <b>Vial ISO 8362-1 2R-1</b>		Creator: <b>Bálint Szabados</b>		Product drawing <b>SCHOTT</b> <b>forma vitrum</b>
Drawing number: <b>10000004995</b>		Approved: <b>Lajos Pungor</b>		
		Status: <b>RD</b>	<b>12.03.2010</b>	
<div>Drawing ID:10000004995-000/00</div> <div>NOTE: Linear dimensions are in millimeter</div>				

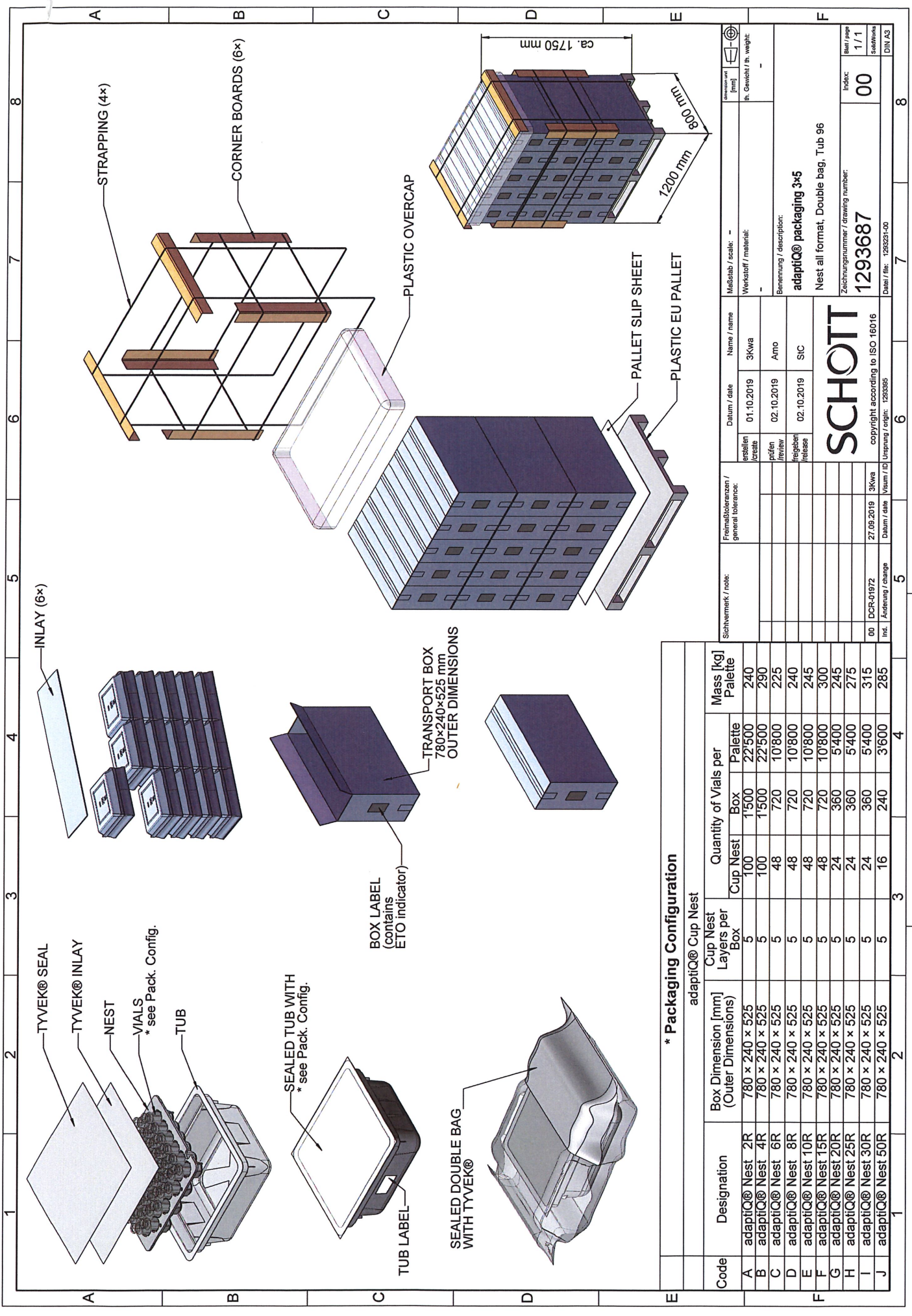




Sichtvermerk / note:		Freimaßtoleranzen / general tolerance:		Datum / date		Name / name		Maßstab / scale: 1:5 (1:2)		dimension unit [mm]	
		DIN 16901 - 130		erstellen /create	13.01.2015	StC		Werkstoff / material: PS		th. Gewicht / th. weight: [g] 156.81	
				prüfen /review	13.01.2015	Gin		Benennung / description:  <b>Tub N96 white</b>  SYG PG TUB 096 WHI			
				freigeben /release	13.01.2015	Fis					
14	DCR-00712	13.01.2015	StC	<b>SCHOTT</b>  copyright according to ISO 16016		Zeichnungsnummer / drawing number:  <b>223795</b>					
13	DCR-00643	29.09.2014	StC								
12	DCR-00632	23.09.2014	Kma								
11	DCR-00592	01.07.2014	Kma								
10	DCR-00575	18.06.2014	Kma								
Ind.	Änderung / change	Datum / date	Visum / ID	Ursprung / origin:		Datei / file: 223795-13			Model Index : 14		DIN A4
									Index: <b>14</b>		Blatt / pag 1 / 1  SolidWorks

Customer

Doc ID: PPD-03-202-F01



**\* Packaging Configuration**

adaptIQ® Cup Nest									
Code	Designation	Box Dimension [mm] (Outer Dimensions)	Cup Nest			Quantity of Vials per			Mass [kg] Palette
			Layers	Box	Box	Cup	Nest	Box	
A	adaptIQ® Nest 2R	780 x 240 x 525	5	5	1'500	100	1'500	22'500	240
B	adaptIQ® Nest 4R	780 x 240 x 525	5	5	1'500	100	1'500	22'500	290
C	adaptIQ® Nest 6R	780 x 240 x 525	5	5	720	48	720	10'800	225
D	adaptIQ® Nest 8R	780 x 240 x 525	5	5	720	48	720	10'800	240
E	adaptIQ® Nest 10R	780 x 240 x 525	5	5	720	48	720	10'800	245
F	adaptIQ® Nest 15R	780 x 240 x 525	5	5	720	48	720	10'800	300
G	adaptIQ® Nest 20R	780 x 240 x 525	5	5	360	24	360	5'400	245
H	adaptIQ® Nest 25R	780 x 240 x 525	5	5	360	24	360	5'400	275
I	adaptIQ® Nest 30R	780 x 240 x 525	5	5	360	24	360	5'400	315
J	adaptIQ® Nest 50R	780 x 240 x 525	5	5	16	16	240	3'600	285

Dimension unit [mm]		Maßstab / scale: -		Name / name 3Kwa		Datum / date 01.10.2019		erstellen / create 	
Th. Gewicht / th. weight: -		Werkstoff / material: -		Amt 02.10.2019		prüfen / review 		freigeben / release 	
Benennung / description: <b>adaptIQ® packaging 3x5</b> Nest all format, Double bag, Tub 96		Zeichnungsnummer / drawing number: <b>1293687</b>		SIC		Datum / date 27.09.2019		Freisetzen / release 	
Index: <b>00</b>		Blatt / page <b>1 / 1</b>		Scale/works		Datum / date 02.10.2019		Freisetzen / release 	
Zeichnungsnummer / drawing number: <b>1293687</b>		Copyright according to ISO 16016 copyright according to ISO 16016		Ursprung / origin: 1293685		Datum / date 02.10.2019		Freisetzen / release 	
Datum / date 02.10.2019		Ursprung / origin: 1293685		Datum / date 02.10.2019		Freisetzen / release 		Datum / date 02.10.2019	

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