

Ref Doc: PSD0014		No.: BAISOX & BAISO35		Rev. 8	
Product:	Bottle Adaptor- Bulk Non-Sterile		Application:	Enteral	
Technical Qualification					
Raw Materials:	Body - LDPE		Pigment - ID13018-PP/PE		
Packing:	Primary - PE Bag				
	Secondary - Hard Corrugated Paper				
	Tertiary - Double Corrugated Paper				
Regulatory:	Class I				
Others:	Shelf Life – 5 years				
Products:					
Code:	Description:				
BAISO1	Enteral Bottle Adaptor Size 1# (12mm-15mm) BNS				
BAISO2	Enteral Bottle Adaptor Size 2# (14mm-16.5mm) BNS				
BAISO3	Enteral Bottle Adaptor Size 3# (17mm-20.5mm) BNS				
BAISO35	Enteral Bottle Adaptor Size 3.5# (19mm-23mm) BNS				
BAISO4	Enteral Bottle Adaptor Size 4# (24mm-26mm) BNS				
Intended Use:					
Used with ISO 80369-3 ENFit® Enteral syringes for putting into bottles and drawing enteral feed or medication from a bottle. This product is single use only.					
Using Recommendations:					
N/A					
Pictures:					
					

Packaging:			
Code:		Packing:	Units:
BAISO1	Primary – Bag 170mm(H) x 140mm(D)		100
	Secondary – Shelf Box 50mm(H) x 105mm(W) x 115mm(D)		100
	Tertiary – Shipper Box 280mm(H) x 360mm(W) x 440mm(D)		6000
BAISO2	Primary – Bag 190mm(H) x 140mm(D)		100
	Secondary – Shelf Box 50mm(H) x 105mm(W) x 150mm(D)		100
	Tertiary – Shipper Box 230mm(H) x 465mm(W) x 545mm(D)		6000
BAISO3	Primary – Bag 250mm(H) x 140mm(D)		100
	Secondary – Shelf Box 50mm(H) x 105mm(W) x 210mm(D)		100
	Tertiary – Shipper Box 230mm(H) x 330mm(W) x 435mm(D)		2400
BAISO35	Primary – Bag 290mm(H) x 140mm(D)		100
	Secondary – Shelf Box 55mm(H) x 105mm(W) x 250mm(D)		100
	Tertiary – Shipper Box 250mm(H) x 330mm(W) x 515mm(D)		2400
BAISO4	Primary – Bag 330mm(H) x 140mm(D)		100
	Secondary – Shelf Box 60mm(H) x 105mm(W) x 270mm(D)		100
	Tertiary – Shipper Box 260mm(H) x 330mm(W) x 555mm(D)		2400
Code:	GTIN Primary:	GTIN Secondary:	GTIN Tertiary:
BAISO1	05060460845554	05060460845561	05060460845578
BAISO2	05060460845585	05060460845592	05060460845608
BAISO3	05060460845615	05060460845622	05060460845639
BAISO35	05060460848074	05060460848081	05060460848098
BAISO4	05060460845646	05060460845653	05060460845660
Code:	Quantity per Pallet:	Pallet Dimensions:	
BAISO1	96000	1200 mm x 800 mm	
BAISO2	48000	1200 mm x 800 mm	
BAISO3	48000	1200 mm x 800 mm	
BAISO35	38400	1200 mm x 800 mm	
BAISO4	38400	1200 mm x 800 mm	

Drawings:

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DIMENSIONS THE ON THE
 DRAWING NOT TO SCALE

**Description: Primary Artwork****Figure 1: BAISO1**

*** Variations: BAISO2, BAISO3, BAISO35, BAISO4 ***

ISOSAF™
Size 1: 12 - 15mm
Medicine Bottle Adaptor
ISO 80369-3 ENFit®

Bottle adaptors are not interchangeable between medicine bottles once in use; use one bottle adaptor per medicine bottle, dispose once detached.









Rx Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Symbol glossary available at www.gbukgroup.com
 Not made with natural rubber latex.


GBUK
 ENHANCING PATIENT CARE

Bulk Pack**100 units**

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 Wirtschaftsprüfungsgesellschaft
 Im Klapperhof 7-23, 50670 Köln, Germany

EU REP

QualRep Services BV
 Utrechtseweg 310 B42, 6812 AR Arnhem, The Netherlands

CH REP

Swiss AR Services AG
 Industriestrasse 47, 6300 Zug, Switzerland

REF

BAISO1

LOT

123456



YYYY-MM-DD



YYYY-MM-DD

Made in **XXXXX**.

EXAMPLE
 BARCODE

(01)05060460845561
(17)YYMMDD
(10)123456

BAISO1-04 2508 16

Figure 1

Description: Secondary Artwork
Figure 2: BAISO1

*** Variations: BAISO2, BAISO3, BAISO35, BAISO4 ***



Figure 2

Description: Tertiary Artwork
Figure 3: BAISO1

*** Variations: BAISO2, BAISO3, BAISO35, BAISO4 ***


REF BAISO1

 ISOSAF™ Medicine Bottle Adaptor
 ISO 80369-3 ENFit®

Size 1: 12 - 15mm
LOT 123456
YYYY-MM-DD
YYYY-MM-DD

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 QualRep Services BV
 Utrechtseweg 310 842
 6812 AR Arnhem,
 The Netherlands

 Swiss AR Services AG
 Industriestrasse 47,
 6300 Zug, Switzerland

 Quantity:
6000 units

 Weight:
XX kg
XX lb XX oz

Made in XXXXX

Bulk Pack

Rx Only Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

 Symbol glossary available at www.gbukgroup.com

Not made with natural rubber latex.

 EXAMPLE
 BARCODE

 (01)05060460845578
 (17)YYMMDD
 (10)123456

BAISO1-08 2508 16


REF BAISO1

 ISOSAF™ Medicine Bottle Adaptor
 ISO 80369-3 ENFit®

Size 1: 12 - 15mm
LOT 123456
YYYY-MM-DD
YYYY-MM-DD

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 6812 AR Arnhem,
 The Netherlands

 Swiss AR Services AG
 Industriestrasse 47,
 6300 Zug, Switzerland

 Quantity:
6000 units

 Weight:
XX kg
XX lb XX oz

Made in XXXXX

Bulk Pack

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 Symbol glossary available at www.gbukgroup.com

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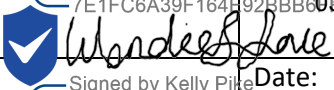
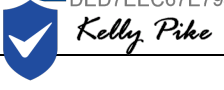
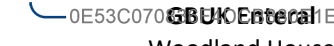
 EXAMPLE
 BARCODE

 (01)05060460845578
 (17)YYMMDD
 (10)123456

BAISO1-08 2508 16

Enteral Data Sheet

Revision 4.1

Modified by:	Name: Nicola Neal	Signature:  Signed by Nicola Neal	Date: 03-Dec-25 I am the author of this document 03-Dec-25 9:12:56 AM GMT
Reviewed by:	Name: Wendie Love	Signature:  Signed by Wendie Love 7E1FC6A39F164B92BB66034D4C4E	Date: 03-Dec-25 I have reviewed this document 03-Dec-25 9:15:32 AM GMT
Quality Approval:	Name: Kelly Pike	Signature:  Signed by Kelly Pike DED7EEC67E794E1A961A034D4C4E	Date: 03-Dec-25 I approve this document 03-Dec-25 9:17:15 AM GMT
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