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|--|--|--|--|-------------------------|--|
| Ref Doc: PSD0014 | | No.: BAISOX-S & BAISO35-S | | Rev. 11 | |
| Product: | | Bottle Adaptor | | Application: | |
| | | | | Enteral | |
| Technical Qualification | | | | | |
| Raw Materials: | | Body - LDPE | | Pigment - ID13018-PP/PE | |
| | | Tether, if present - Thermoplastic polyurethane | | | |
| Packing: | | Primary - Medical Dialysis Paper, PP/PE Medical composite packaging film | | | |
| | | Secondary - Hard Corrugated Paper | | | |
| | | Tertiary - Double Corrugated Paper | | | |
| Regulatory: | | Class I | | | |
| Others: | | Shelf Life – 5 years | | | |
| Products: | | | | | |
| Code: | | Description: | | | |
| BAISO0-S | | Enteral Bottle Adaptor & Tether (10mm) Single Blister, Non-Sterile | | | |
| BAISO1-S | | Enteral Bottle Adaptor Size 1# (12mm-15mm) Single Blister, Non-Sterile | | | |
| BAISO2-S | | Enteral Bottle Adaptor Size 2# (14mm-16.5mm) Single Blister, Non-Sterile | | | |
| BAISO3-S | | Enteral Bottle Adaptor Size 3# (17mm-20.5mm) Single Blister, Non-Sterile | | | |
| BAISO35-S | | Enteral Bottle Adaptor Size 3.5# (19mm-23mm) Single Blister, Non-Sterile | | | |
| BAISO4-S | | Enteral Bottle Adaptor Size 4# (24mm-26mm) Single Blister, Non-Sterile | | | |
| 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. | | | | | |
| Pictures: | | | | | |
|  | | | | | |

Enteral Data Sheet

Revision 3.1



| Packaging: | | | |
|------------|---|-----------------|----------------|
| Code: | Packing: | | Units: |
| BAISO0-S | Primary – Blister 48mm(W) x 60mm(D) | | 1 |
| | Secondary – Shelf Box 123mm(H) x 185mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 270mm(H) x 390mm(W) x 600mm(D) | | 1200 |
| BAISO1-S | Primary – Blister 38mm(W) x 48mm(D) | | 1 |
| | Secondary – Shelf Box 77mm(H) x 190mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 340mm(H) x 400mm(W) x 600mm(D) | | 2400 |
| BAISO2-S | Primary – Blister 38mm(W) x 48mm(D) | | 1 |
| | Secondary – Shelf Box 77mm(H) x 190mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 340mm(H) x 400mm(W) x 600mm(D) | | 2400 |
| BAISO3-S | Primary – Blister 48mm(W) x 60mm(D) | | 1 |
| | Secondary – Shelf Box 123mm(H) x 185mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 270mm(H) x 390mm(W) x 600mm(D) | | 1200 |
| BAISO35-S | Primary – Blister 48mm(W) x 60mm(D) | | 1 |
| | Secondary – Shelf Box 123mm(H) x 185mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 270mm(H) x 390mm(W) x 600mm(D) | | 1200 |
| BAISO4-S | Primary – Blister 48mm(W) x 60mm(D) | | 1 |
| | Secondary – Shelf Box 123mm(H) x 185mm(W) x 192mm(D) | | 100 |
| | Tertiary – Shipper Carton 270mm(H) x 390mm(W) x 600mm(D) | | 1200 |
| | | | |
| Code: | GTIN Primary: | GTIN Secondary: | GTIN Tertiary: |
| BAISO0-S | 05060590886540 | 05060590886557 | 05060590886564 |
| BAISO1-S | 05060460848104 | 05060460848111 | 05060460848128 |
| BAISO2-S | 05060460848135 | 05060460848142 | 05060460848159 |
| BAISO3-S | 05060460848166 | 05060460848173 | 05060460848180 |
| BAISO35-S | 05060460848197 | 05060460848203 | 05060460848210 |
| BAISO4-S | 05060460848227 | 05060460848234 | 05060460848241 |

Enteral Data Sheet

Revision 3.1

| Code: | Quantity per Pallet: | Pallet Dimensions: |
|-----------|----------------------|--------------------|
| BAISO0-S | 19200 | 1200 mm x 800 mm |
| BAISO1-S | 28800 | 1200 mm x 800 mm |
| BAISO2-S | 28800 | 1200 mm x 800 mm |
| BAISO3-S | 19200 | 1200 mm x 800 mm |
| BAISO35-S | 19200 | 1200 mm x 800 mm |
| BAISO4-S | 19200 | 1200 mm x 800 mm |

Drawings:

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DIMENSIONS THE ON THE DRAWING NOT TO SCALE



Description: Primary Artwork

Figure 1: BAISO0-S

*** Variations: BAISO1-S, BAISO2-S, BAISO3-S, BAISO35-S, BAISO4-S

ISOSAF™ Made in XXXXX

Medicine Bottle Adaptor & Tether
Size 0: 8 - 10mm ISO 80369-3 ENFit®

 **MD**

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

CE UK CA

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

CH REP **Swiss AR Services AG**
Industriestrasse 47, 6300 Zug, Switzerland

REF **BAISO0-S**
LOT **123456**
YYYY-MM-DD
YYYY-MM-DD
(01)05060590886540
(17)YYMMDD (10)123456

EXAMPLE BARCODE

BAISO0-S-04 2410 14

Figure 1

Description: **Secondary Artwork**

Figure 2: BAISO0-S

*** Variations: BAISO1-S, BAISO2-S, BAISO3-S, BAISO35-S, BAISO4-S

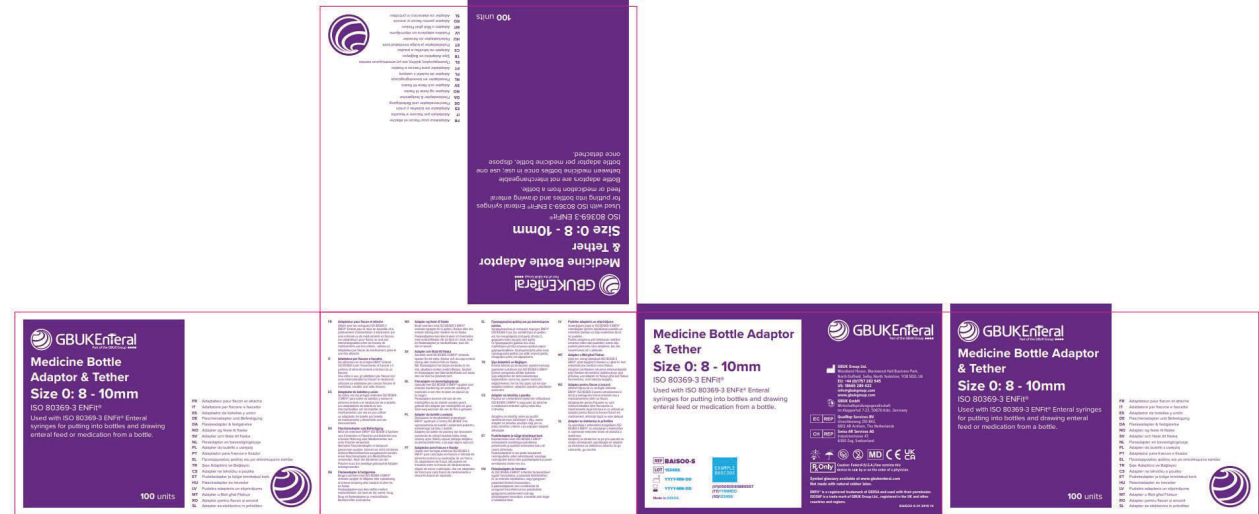


Figure 2

| | |
|--------------|------------------|
| Description: | Tertiary Artwork |
|--------------|------------------|

Figure 3: BAIS00-S

*** Variations: BAIS01-S, BAIS02-S, BAIS03-S, BAIS035-S, BAIS04-S



**ISOSAF™ Medicine Bottle
Adaptor & Tether**
ISO 80369-3 ENFit®
Size 0: 8 - 10mm

LOT 123456

YYYY-MM-DD
YYYY-MM-DD

Made in XXXXX



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Symbol glossary available at www.gbukenteral.com

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QualRep Services BV
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The Netherlands

Swiss AR Services AG
Industriestrasse 47,
6300 Zug, Switzerland

Quantity:
1200 units

Weight:
XX kg
XX lb XX oz



**ISOSAF™ Medicine Bottle
Adaptor & Tether**
ISO 80369-3 ENFit®
Size 0: 8 - 10mm

LOT 123456

YYYY-MM-DD
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Industriestrasse 47,
6300 Zug, Switzerland

Quantity:
1200 units

Weight:
XX kg
XX lb XX oz



Figure 3

| | | | |
|---|---------------------------|---|-------------------------------------|
| Modified by: | Name: Aleksandra Malek | Signature:  Signed by Aleksandra Malek | Date: 30-Jan-25 3:02:38 PM GMT |
| Reviewed by: | Name: Nicola Neal | Signature:  Signed by Nicola Neal | Date: 30-Jan-25 3:56:31 PM GMT |
|  <p>GBUK Enteral is a trading name of GBUK Enteral Ltd. GBUK Enteral Ltd. Is part of GBUK Group Ltd.</p> | | <p>GBUK Enteral Woodland House Blackwood Hall Business Park North Duffield, North Yorkshire YO8 5DD, UK</p> <p>TEL: +44 (0) 1757 282 945 https://www.gbukgroup.com/ https://www.gbukgroup.com/brands/gbuk-enteral/</p> | |