

Declaration of Conformity		
Technical file	Enteral / Oral Bottle Adaptors	
Document Reference	DOC-112	
Issue	5.0	Page 1 of 2



Declaration of Conformity

Legal Manufacturer	<p>GBUK Group Ltd Trading as:</p> <p>GBUK Ltd GBUK Healthcare GBUK Banana GBUK Enteral Ltd Enteral UK Ltd Intervene Group Ltd</p> <p>Woodland House Blackwood Hall Business Park North Duffield, Selby North Yorkshire YO8 5DD United Kingdom</p>
General Product Name	Enteral / Oral Bottle Adaptors
Product Variants	See attached Appendix
Compliance Statement	We hereby declare that the above mentioned devices comply with the legislation of the United Kingdom transposing European Medical Devices Directive 93/42/EEC
Classification Rule	Rule 1, Annex IX, for Class I Devices
Assessment Route	Annex VII for Class I Devices

Declaration of Conformity		
Technical file	Enteral / Oral Bottle Adaptors	
Document Reference	DOC-112	
Issue	5.0	Page 2 of 2



Signed:

Name: Dr Stephen Curran

Position: Regulatory Affairs Manager

Date: 07 August 2019

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Declaration of Conformity		
Technical file	Enteral / Oral Bottle Adaptors	
Document Reference	DOC-112	
Issue	5.0	Page 3 of 2

Appendix

Product Catalogue Number	Product Description	Classification
BAISO1	Enteral Bottle Adapter Size 1# (12mm – 15mm) 100 units per bag	I
BAISO2	Enteral Bottle Adapter Size 2# (14mm – 16.5mm) 100 units per bag	I
BAISO3	Enteral Bottle Adapter Size 3# (17mm - 20.5mm) 100 units per bag	I
BAISO35	Enteral Bottle Adapter Size 3.5# (19mm – 23mm) 100 units per bag	I
BAISO4	Enteral Bottle Adapter Size 4# (24mm – 26mm) 100 units per bag	I
BAISO1-S	Enteral Bottle Adapter Size 1# (12mm – 15mm) 100 units per bag, singly blistered	I
BAISO2-S	Enteral Bottle Adapter Size 2# (14mm – 16.5mm) 100 units per bag, singly blistered	I
BAISO3-S	Enteral Bottle Adapter Size 3# (17mm – 20.5mm) 100 units per bag, singly blistered	I
BAISO35-S	Enteral Bottle Adapter Size 3.5# (19mm – 23mm) 100 units per bag, singly blistered	I
BAISO4-S	Enteral Bottle Adapter Size 4# (24mm – 26mm) 100 units per bag, singly blistered	I
OBA-A	Oral Bottle Adapter Size 1# (12mm – 16mm) (100 x 1 units)	I
OBA-B	Oral Bottle Adapter Size 2# (17mm-20mm) (100 x 1 units)	I
OBA-C	Oral Bottle Adapter Size 3# (21mm-23mm) (100 x 1 units)	I
OBA-D	Oral Bottle Adapter Size 4# (24mm – 28mm) (100 x 1 units)	I
ISO2UAD	Funnel to ENFit adaptor with cap	I