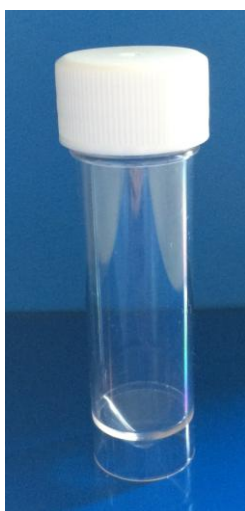


TECHNICAL DATA SHEET 500-1000-301

Date of issue: 09.06.2015

Product Code: 500-1000-301

Description

30ml Universal container in clear polystyrene with a high density polyethylene screw cap with integral low density expanded polyethylene seal.

Declaration of Conformity

This product comes under the remit of the In Vitro Medical Devices Directive 98/79/EC and is classed as a general IVD product under Annex III (specimen receptacle as per article 1(b) of the directive).

As the manufacturer we hereby declare that the requirements and obligations, as described in Annex 111 sections 2 to 5 of the Directive have been met.

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Authorised By: R. Conway

Microbiological Status	Manufactured using an automated aseptic manufacturing system under laminar flow HEPA filtration.
Standard to which the product conforms	BS EN 14254:2004
95kPa Pressure leak test to which the product conforms	To test method 49 CFR 178.605, IATA DGR 6.3.5 Ref project H20708-19 HQE2 1 Feb 2008
Material of construction (body)	Polystyrene. Conforms to EC No 1935/2004 and EU no 10/2011
Cap Liner Material	Expanded low density polyethylene. Conforms to EU2002/72/EC and 94/62/EC
Material of construction (Cap shell)	High Density polyethylene.
Volume (ml)	25ml, 30ml (brim capacity)
Bottle Dimensions (mm)	91 x 25 (approx)
Operational temperature Range	-10 to 65 Degrees Centigrade
Inner Pack Quantity	400
Outer Box Quantity	400