

Product Procedure Specifications Sheet

Specification Sheet No	SSN-PPK(22)-009		
Product Name	60 ml Gallipot		
Product Description	36519012 (Rev 2)		
Range	365 Healthcare		
Manufacturer	Mediq Healthcare UK Ltd		
Packaging	60 ml Gallipot		
Sterilisation	36519012 (rev 2)		
Issue Date	21st May 2024	Version No	R02



Intended use	This range consists of general supplementary items which can be used on its own or in addition to other procedure packs for the required clinical procedure.
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Pack content				
Item	Product code	Quantity	Dimensions	Material
Gallipot	2401	1	60ml	Polypropylene

Quality Certification	ISO 13485:2016		
Device Classification	Class Is	Rule	Article 22
Conformity Route	Medical Devices Regulation (EU) 2017/745 Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)		
Storage conditions	Store in a cool dry place away from heat and direct sunlight.		
Shelf life	5 years if stored under recommended storage conditions		
Contraindications/Warnings	None		
Markings	Product Name, REF, 365 Logo and Address Lot Number, Manufacturing Date, Expiry Date Medical Device, Single Use, EO Sterile, Single sterile barrier, do not use if package damaged, Keep dry and away from sunlight, CE, ECREP, Manufacturer		
Additional information	Products are latex and phthalate free. Products contain no hazardous substances. Products contain no medical substances.		
Medical Device and Reporting System: Incidents caused by this device must be reported immediately to our offices.			

The information provided within this Specification Sheet is correct as of last revision but it is subject to change without notice.

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Document Reference	Document Name	Reviewed By	Approved By	Revision Number	Issue Date
DMS 04-004-03	Procedure Pack Specification Sheet	Jack Wong	Racheal Begg	R02	03 rd April 2024

Amendment Record

This procedure is reviewed to ensure its continuing relevance to the system and process that it describes. A record of contextual additions or omissions is given below. This revision history lists all changes to this document, the date of each revision, and the reason for each revision.

Revision Number	Revision Date	Reason for Revision	Updated by
R01	15/09/2023	Update to Mediq Healthcare UK brand replacing DSN688	Racheal Begg
R02	21/05/2024	Update Mediq Healthcare UK address	Jack Wong

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