

Product Identification	
Name	Syringe Water w/Glycerine10%, Luer,10ml-Fill.10ml-Bulk pack*S
Reference	3040008 (Former:14318BS)
Product family	Sterile Syringes with water 10% glycerine
Brand	Steriflush [®]
Intended use	Intended to fill the balloon from a balloon catheter. Do not use for injection.
Sterilization	Radiation

Physical and chemical characterization	
Physical state	Liquid
Appearance	Colourless/Clear
Odor	Odorless
Shelf life	3 years from the manufacturing date. The expire date will be indicated on the packaging.
Storage conditions	Keep away from sunlight and keep dry.

Composition	
Water with 10% glycerin	
Internal reference	238012
Glycerin concentration	9,50 g/100 mL – 10,50 g/100 mL
pH	4,5 – 7,5
Endotoxins	≤ 4,5 UI/ mL
Bioburden	< 50 CFU/ mL

Compliance: ISO 13485, European Pharmacopeia.

Syringe	
Internal reference	55111
Volume	10ml
Barrel	Polypropylene
Plunger	Polypropylene, green
Plunger jacket	Isoprene rubber
Printed	Yes

Compliance Standards: ISO 9001, ISO 14971, ISO 11737, ISO 80369, ISO 7886, ISO 10993

Syringe cap	
Internal reference	1851
Material	Polyethylene
Colour	Transparent

Packaging	
Packaging level	Sterile single pack
Carton box with bag	200pcs

Hazards identification	
Eye contact	No adverse effects expected
Skin contact	No adverse effects expected
Inhalation	No adverse effects expected
Ingestion	No adverse effects expected
Long-term effects	Not know
Toxicity	Non-toxic
Risks of fire or explosion	No adverse effects expected

Environmental and disposal considerations

Not regarded as dangerous for the environmental. Dispose of material according to local, regional and national regulations.

Compliance Regulations & Standards

Regulation (EU) 2017/745 (as applicable), Directive 93/42/EEC, EN ISO 14971, EN ISO 15223-1, EN ISO 10993-1, EN ISO 11737, EN ISO 11137

