



## 20 ml PP Bottle



### General Features

Aquare 20 ml is a sterile, physiological irrigation solution for ophthalmic procedures.

For the irrigation of the anterior chamber during cataract surgery and for other intraocular or extraocular procedures, such as therapeutic or diagnostic measures, where irrigation or retention of moisture is required.

### Product Description

Composition	<b>1 ml solution contains:</b> Sodium chloride 6.40 mg Potassium chloride 0.75 mg Calcium chloride 2 H <sub>2</sub> O 0.48 mg Magnesium chloride 6 H <sub>2</sub> O 0.30 mg Sodium acetate 3 H <sub>2</sub> O 3.90 mg Sodium citrate 2 H <sub>2</sub> O 1.70 mg	<b>Excipients:</b> Water for injection, hydrochloric acid (for pH adjustment) Unbuffered solution (according to EN ISO 16671)
pH	6.8 – 7.6	
Density	1.005 - 1.010 g/ml	
Refractive index	1.3340 - 1.3360	
Extractable Volume	20 ml	
Source	Water for Injection + salts	
Osmolality	295 - 315 mOsmol/kg	
Transmittance	min. 95% between 300 and 1100 nm	
BVI product code	1398	

### Product Information

Sterile Irrigating Solution	Name	General Device Description	Qty/Bx	SKU#
	AQUARE 20 ml PP	Sterile Irrigating Solution	50	1398

## Product Information

Packaging	General Device Description
50 filled 20 ml bottle of BSS individually packaged in a soft pouch. 1 multilanguage Instructions for Use	Name AQURE 20 ml PP Reference Code CT 230 = "Ophthalmic device" GTIN 1 376013064 054 8 GMDN 60756 (Eye irrigation solution, synthetic)
Manufacturer	Product Class
MTP Medical Technologies Kunstseidenstrasse 4 01796 Pirna, Germany	Class IIa sterile, single use
OR Requirements	Shelf Life
For the irrigation of the anterior chamber during cataract surgery and for other intraocular or extraocular procedures, such as therapeutic or diagnostic measures, where irrigation or retention of moisture is required. It is intended for HCP.	Two (2) years from manufacturing date
Certification Information	Absence of
EC Certification: D1366200013 CE mark: CE 0483 FDA approval: NA Notified Body: medical device certification GmbH (mdc)  ISO 13485:2016	Substance derived from human origin, animal origin. Transmissible Spongiform Encephalopathy (TSE). Bovine Spongiform Encephalopathy (BSE).
Sterilisation	Packaging Material
Moist-Heat sterilization (Autoclave)	Primary: Polypropylene bottle in a soft pouch Secondary: Carton box
Weight of the Device	Storage & Transportation
23.25 g	Storage: No special storage condition Transportation: No special transportation condition

### Contact Information:

[www.bvimedical.com/customer-support](http://www.bvimedical.com/customer-support)

