



# Datasheet

STAXS® Reference	Description
IS-3005	DOTCH® Puru® Ball-point, black, double bagged in HDPE, 1 pc/inner bag, 5 inner bags/outer bag, 4 outer bags/box, sterile

The supplier is responsible for the information and data mentioned on the datasheet.  
This version is the latest version received from the supplier.

## DOTCH<sup>®</sup> Puru<sup>®</sup> Ball-point

STAXS<sup>®</sup> Reference : **IS-3005**

**DOTCH<sup>®</sup> Puru<sup>®</sup> Ball-point, black, double bagged in HDPE, 1 pc/inner bag, 5 inner bags/outer bag, 4 outer bags/box, sterile**



### Features & advantages

- Bic<sup>®</sup> ball-point
- Verifiable quality from a guaranteed source
- Continuous bioburden testing
- Packed in an easy-tear HDPE cleanroom bag
- Double packed in ISO 5 cleanroom (ISO 14644-1)
- Validated sterility SAL 10<sup>-6</sup>
- Recommended for ISO 5 cleanrooms and higher

### Physical characteristics

Type	Fountain pen	Colour	Black
		Line width	0,7mm

### Technical data

Shelf life	Years	2*
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\* From date of manufacture

Revision date : 05/12/2017



SCIENTIFIC CREDIBILITY

## DOTCH® Puru® Ball-point

STAXS® Reference : **IS-3005**

### Packaging

Product	Ref. No.	Pieces/ inner bag	Inner bags/ outer bag	Outer bags/box	Box size	Box weight
DOTCH® Puru® Ball-point	IS-3005	1	5	4	33x24x4,5cm	

### Notes:

- Packed in HDPE cleanroom pouches with an easy-tear opening
- Box liner present in the box
- Minimum sales unit: 1 box
- Sterilization indicator on the inner label and on the box
- Production date, lot number and expiry date can be found on the inner label and on the box

### Storage

- Store in dry, clean conditions in the original packaging and keep out of direct sunlight, high temperatures and solvent vapors
- Store between 5°C and 40°C

### Certification

- Produced in conformity with ISO 9001:2008
- Bioburden and dosing (Periodic Dose Audit) checked periodically - ISO 11137-2
- Sterility validated according to ISO 11137-2:2012 AAMI - TR 27:2001 (VDmax<sup>25</sup>)
- Certificate of irradiation (min. irradiation of 25kGy)
- Shelf life of 2 years from date of manufacture - ISO 11137-2 and ASTM F 1980-07

Revision date : 05/12/2017



# Datasheet

STAXS® Reference	Description
IS-3006	DOTCH® Puru® Ball-point, blue, double bagged in HDPE, 1 pc/inner bag, 5 inner bags/outer bag, 4 outer bags/box, sterile

The supplier is responsible for the information and data mentioned on the datasheet.  
This version is the latest version received from the supplier.

**DOTCH<sup>®</sup> Puru<sup>®</sup> Ball-point**

STAXS<sup>®</sup> Reference : **IS-3006**

**DOTCH<sup>®</sup> Puru<sup>®</sup> Ball-point, blue, double bagged in HDPE, 1 pc/inner bag, 5 inner bags/outer bag, 4 outer bags/box, sterile**



**Features & advantages**

- Bic<sup>®</sup> ball-point
- Verifiable quality from a guaranteed source
- Continuous bioburden testing
- Packed in an easy-tear HDPE cleanroom bag
- Double packed in ISO 5 cleanroom (ISO 14644-1)
- Validated sterility SAL 10<sup>-6</sup>
- Recommended for ISO 5 cleanrooms and higher

**Physical characteristics**

Type	Fountain pen	Colour	Blue
		Line width	0,7mm

**Technical data**

Shelf life	Years	2*
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\* From date of manufacture

Revision date : 05/12/2017



SCIENTIFIC CREDIBILITY

## DOTCH® Puru® Ball-point

STAXS® Reference : **IS-3006**

### Packaging

Product	Ref. No.	Pieces/ inner bag	Inner bags/ outer bag	Outer bags/box	Box size	Box weight
DOTCH® Puru® Ball-point	IS-3006	1	5	4	33x24x4,5cm	

### Notes:

- Packed in HDPE cleanroom pouches with an easy-tear opening
- Box liner present in the box
- Minimum sales unit: 1 box
- Sterilization indicator on the inner label and on the box
- Production date, lot number and expiry date can be found on the inner label and on the box

### Storage

- Store in dry, clean conditions in the original packaging and keep out of direct sunlight, high temperatures and solvent vapors
- Store between 5°C and 40°C

### Certification

- Produced in conformity with ISO 9001:2008
- Bioburden and dosing (Periodic Dose Audit) checked periodically - ISO 11137-2
- Sterility validated according to ISO 11137-2:2012 AAMI - TR 27:2001 (VDmax<sup>25</sup>)
- Certificate of irradiation (min. irradiation of 25kGy)
- Shelf life of 2 years from date of manufacture - ISO 11137-2 and ASTM F 1980-07

Revision date : 05/12/2017