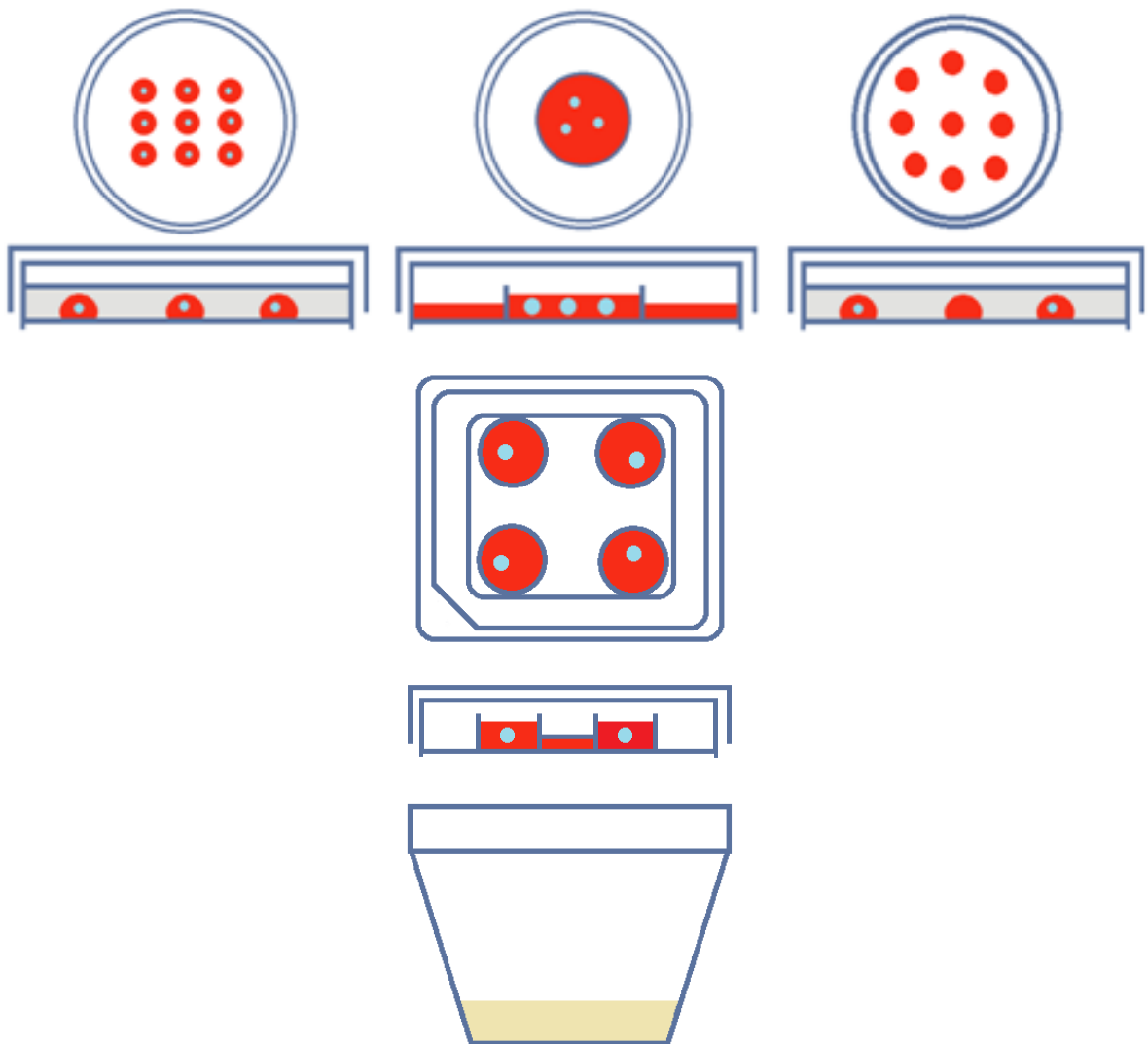




# Instructions for Use



## PRODUCTS

**Oosafe® 4 Well Dish Treated Surface**

**Oosafe® 4 Well Dish Non-Treated Surface**

**Oosafe® 6 Well Dish**

**Oosafe® ICSI/IMSI Dish**

**Oosafe® Center Well Dish With 2 Compartments**

**Oosafe® 35mm High Wall Dish**

**Oosafe® 100mm Dish**

**Oosafe® 60mm Dish**

**Oosafe® Sperm Collection Cup, 80ml**

**Oosafe® Centrifuge Tube, 15ml**

**Oosafe® OPU Tube, 14ml**

**Oosafe® Andrology Tube, 5ml**

### **Attention!**

- Check the expiration date on the label.
- Optimal storage temperature is 20-30°C.
- Only for SINGLE use!
- The product is STERILE only if the packaging is intact. After opening the sealing, the product/products cannot stay sterile and cannot be stored anymore. The product/products should be either used up or disposed once after the packaging is opened (and the products are off-gassed).
- Do only use optically perfect and undamaged device.
- All the products are supposed to be used in the controlled clean area. Anything, which has no matter direct or indirect contact with the product should be sufficiently clean.
- Discard the product immediately if the primary packaging is damaged.
- Disposal: Oosafe®Plasticware is recyclable. For the sake of environment, we recommend disposing dishes according to the local regulations.



- Plastic is inflammable, KEEP AWAY FROM FIRE!



- Attention: All the dimensions of the dishes mentioned in the Instruction for Use are the widest outer dimensions, e.g. if the dish has finger area grips, the diameter of the dish includes the width of the grips. The dimension will make it easier for the customers to see if SparMED's products fit the incubators of the lab/clinic.

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## Product: Oosafe® 4 Well Dish Treated Surface

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Description (L x W x H) <sup>1</sup> (mm)	Prod. No.	Qty/pc	Qty/cs
65.8 x 65.8 x 12.0, 4 Well Dish	OOPW-FW02	1	240
65.8 x 65.8 x 12.0, 4 Well Dish	OOPW-FW03	4	120

### Intended use

Oosafe® 4 Well Dish with treated surface is suitable for culturing cells which need to grow adherently.

### Handling

The packaging of Oosafe® 4 Well Dish with treated surface, including single pack and multipack, is breathable material with no VOC release after opening. After opening the sealing, the dishes can be directly put into use.

To culture the cells, fill the wells with medium, and place the dish in the incubator or in the heating unit prior to use. The recommended medium volume per well is 0,5ml, and the recommended medium volume in the main chamber is 1ml.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

<sup>1</sup> L x W x H: Length x Width x Height

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## Product: Oosafe<sup>®</sup> 4 Well Dish Non-Treated Surface

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Description (L x W x H) (mm)	Prod. No.	Qty/pc	Qty/cs
65.8 x 65.8 x 12.0, 4 Well Dish	OOPW-FW01	1	240
65.8 x 65.8 x 12.0, 4 Well Dish	OOPW-FW04	4	120

### Intended use

Oosafe<sup>®</sup> 4 Well Dish with non-treated surface is suitable for culturing cells which can grow in the medium without attaching to the surface.

Cell culturing and testing the growth of the cells.

### Safety

Observe the expiry date and the storage condition on the label.

Do only use optically perfect and undamaged plasticware.

### Handling

The package of Oosafe<sup>®</sup> 4 Well Dish with non-treated surface, including single pack and multipack, is breathable material with no VOC release after opening. After opening the sealing, the dishes can be directly put into use.

To culture the cells, fill the wells with medium, and place the dish in the incubator or in the heating unit prior to use. The recommended medium volume per well is 0,5ml, and the recommended medium volume in the main chamber is 1ml.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe<sup>®</sup> 6 Well Dish

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Description (L x W x H) (mm)	Prod. No.	Qty/pc	Qty/cs
77.2 x 64.4 x 12.8, 6 Well Dish*	OOPW-SW02	1	240
77.2 x 64.4 x 12.8, 6 Well Dish*	OOPW-SW03	4	120

### Intended use

Oosafe<sup>®</sup> 6 Well Dish is suitable for culturing cells and testing purposes.

### Handling

The package of Oosafe<sup>®</sup> 6 Well Dish, including single pack and multipack, is breathable material with no VOC release after opening. After opening the sealing, the dishes can be directly put into use.

To culture the cells, fill the wells with medium, and place the dish in the incubator or in the heating unit prior to use.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe® ICSI/IMSI Dish

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Description (D, H) <sup>2</sup> (mm)	Prod. No.	Qty/pc	Qty/cs
51.5, 10.2, ICSI/IMSI Dish	OOPW-IC02	1	240
51.5, 10.2, ICSI/IMSI Dish	OOPW-IC03	10	500

### Intended use

Oosafe® ICSI/IMSI Dish is suitable for choosing the best sperm of the sample. It can be used without oil immersion.

### Handling

Prior to use, open the sealing and leave the dishes to off-gas before use (unless it is a single-pack dish).

Oosafe® ICSI/IMSI Dish packages may be off-gassed by partially opening the sleeve or taking the dishes entirely out of the packaging. In either case, the opened sleeves or dishes must be kept in a sterile environment at ambient temperature and humidity. The dishes should remain covered with the lids until they are loaded with the sample and medium.

Place small droplets on the bottom of the dish. Recommended volume per drop is 5 - 50 µl according to the use purpose. Overlay the drop with oil. The recommended volume is 5 ml.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

Storage Store at room temperature.

<sup>2</sup> D, H: Diameter, Height

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## Product: Oosafe® Center Well Dish With 2 Compartments

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Description (D, H) (mm)	Prod. No.	Qty/pc	Qty/cs
59.0, 15.0, Center Well Dish *	OOPW-CW04	1	240
59.0, 15.0, Center Well Dish *	OOPW-CW05	10	500

\*With 2 Compartments

### Intended use

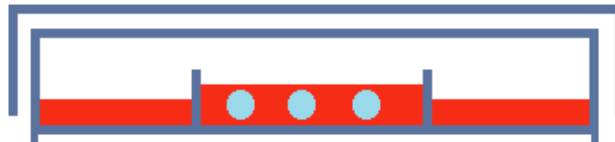
Oosafe® Center Well Dish is suitable for washing the cells and collecting them in the other chambers after washing. It can also be used for other testing purposes.

### Handling

Prior to use, open the sealing and leave the dishes to off-gas before use, unless it is a single-pack dish.

Oosafe® Center Well Dish packages may be off-gassed by partially opening the sleeve or taking the dishes entirely out of the packaging. In either case, the opened sleeves or dishes must be kept in a sterile environment at ambient temperature and humidity. The dishes should remain covered with the lids until they are loaded with the sample and medium.

Fill the center well and the outer chambers with equilibrated medium according to your protocol. The recommended medium volume in the center well is 1ml, and the recommended medium volume in the chamber is 5ml.



When the dish is covered by the lid, the air can still go in and out of the dish.

Discard after use.

### Storage

Store at room temperature.



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## Product: Oosafe<sup>®</sup> 35 mm High Wall Dish

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<u>Description (D, H) (mm)</u>	<u>Prod. No.</u>	<u>Qty/pc</u>	<u>Qty/cs</u>
39.8, 10.7, 35mm High Wall Dish	OOPW-TF03	10	500

### Intended use

Oosafe<sup>®</sup> 35 mm High Wall Dish is suitable for small volume cell culturing and testing.

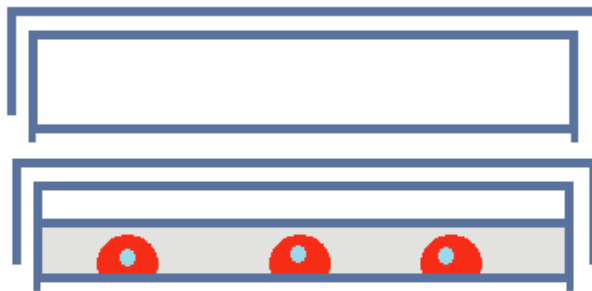
### Handling

Prior to use, open the sealing and leave the dishes to off-gas before use (unless it is a single-pack dish).

Oosafe<sup>®</sup> 35 mm High Wall Dish packages may be off-gassed by partially opening the sleeve or taking the dishes entirely out of the packaging. In either case, the opened sleeves or dishes must be kept in a sterile environment at ambient temperature and humidity. The dishes should remain covered with the lids until they are loaded with the sample and medium.

Place small droplets on the bottom of the dish. The recommended volume per drop is 20-50 µl. Overlay the drop with oil. The recommended volume is 5ml. It is also possible to use the dish entirely instead of only making drops. Use the 2 finger grips to hold the dish securely.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe® 60mm Dish

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Description (D, H) (mm)	Prod. No.	Qty/pc	Qty/cs
59.0, 14.8, 60 mm Dish	OOPW-ST02	1	240
59.0, 14.8, 60 mm Dish	OOPW-ST03	10	500

### Intended use

Oosafe® 60 mm Dish is suitable for medium volume cell culturing and testing.

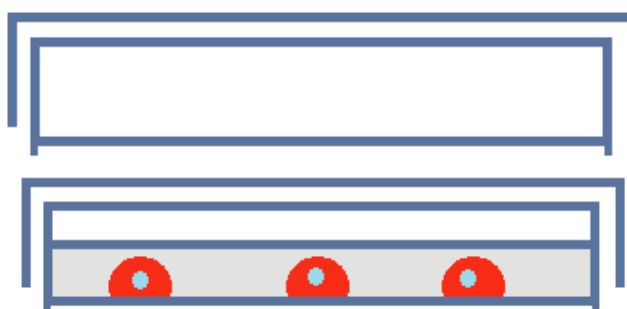
### Handling

Prior to use, open the sealing and leave the dishes to off-gas before use (unless it is a single-pack dish).

Oosafe® 60 mm Dish packages may be off-gassed by partially opening the sleeve or taking the dishes entirely out of the packaging. In either case, the opened sleeves or dishes must be kept in a sterile environment at ambient temperature and humidity. The dishes should remain covered with the lids until they are loaded with the sample and medium.

Place small droplets on the bottom of the dish. The recommended volume per drop is 20-50 µl. Overlay the drop with oil. The recommended volume is 10ml. It is also possible to use the dish entirely instead of only making drops.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe® 100 mm Dish

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Description (D, H) (mm)	Prod. No.	Qty/pc	Qty/cs
91.5, 19.9, 100 mm Dish	OOPW-HD10	10	250

### Intended use

Oosafe® 100 mm Dish is suitable for big volume cell culturing and testing.

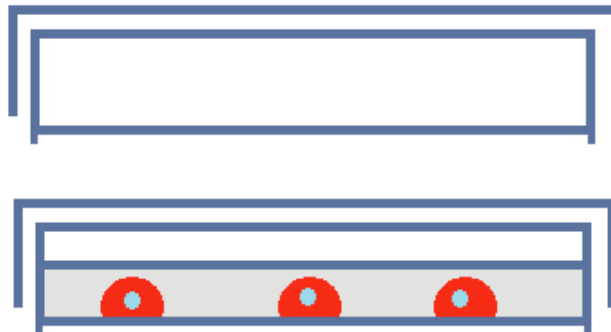
### Handling

Prior to use, open the sealing and leave the dishes to off-gas before use.

Oosafe® 100 mm Dish packages may be off-gassed by partially opening the sleeve or taking the dishes entirely out of the packaging. In either case, the opened sleeves or dishes must be kept in a sterile environment at ambient temperature and humidity. The dishes should remain covered with the lids until they are loaded with the sample and medium.

Place small droplets on the bottom of the dish. The recommended volume per drop is 20-50 µl. Overlay the drop with oil. The recommended volume is 40ml. It is also possible to use the dish entirely instead of only making drops.

When the dish is covered by the lid, the air can still go in and out of the dish.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe<sup>®</sup> Sperm Collection Cup

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Description (volume) (ml)	Prod. No.	Qty/pc	Qty/cs
80, Sperm Collection Cup	OOPW-SC01	1	70

### Intended use

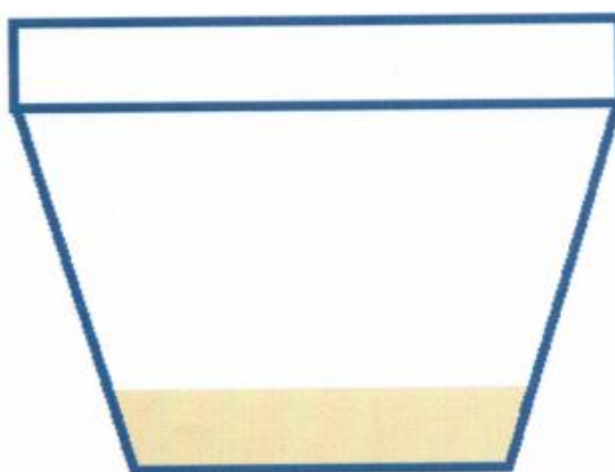
Oosafe<sup>®</sup> Sperm Collection Cup is suitable for sperm collection.

### Handling

The packaging of Oosafe<sup>®</sup> Sperm Collection Cup is breathable material with no VOC release after opening. After opening the sealing, the cup can be directly put into use.

Screw the cap properly to avoid leaking after collecting the sperm.

The cup and the cap are made of Polypropylene. Do not squeeze the cup and the cap too much, otherwise leaking may happen by reason of the cap not being closed properly.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe<sup>®</sup> Centrifuge Tube

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Description (volume) (ml)	Prod. No.	Qty/pc	Qty/cs
15ml, Centrifuge Tube	OOPW-CT01	1	300

### Intended use

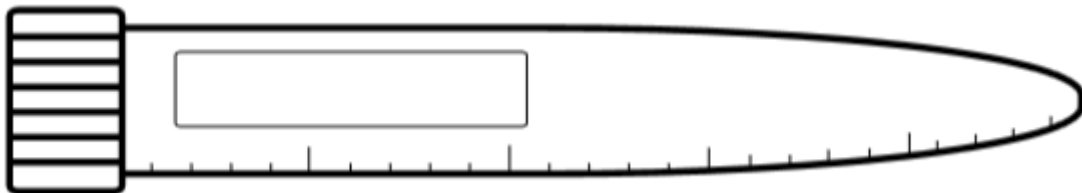
Oosafe<sup>®</sup> Centrifuge Tube is suitable for preparing samples for centrifuge, e.g. human sperm.

### Handling

The package of Oosafe<sup>®</sup> Sperm Collection Cup is breathable material with no VOC release after opening. After opening the sealing, the tube can be directly put into use.

Prepare samples according to the protocol applied. Although the tube can be filled up to 14 ml, the recommended volume for use is between 0.5ml to 13ml. Please close the cap tightly before centrifuging it, and remember to write detailed information on the designated area of the tube.

The cap can be loosely put over the tube for keeping the gas changing. The cap can also be pushed down thoroughly for tight sealing.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe<sup>®</sup> OPU Tube

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Description (volume) (ml)	Prod. No.	Qty/pc	Qty/cs
14ml, OPU Tube	OOPW-OT10	10	500

### Intended use

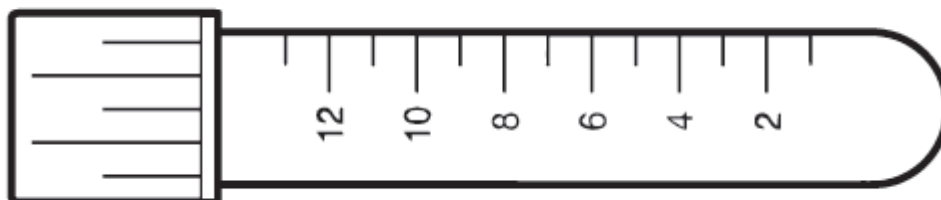
Oosafe<sup>®</sup> OPU Tube is suitable for collecting samples into the tube by using negative pressure or by using ordinary methods.

### Handling

The package of Oosafe<sup>®</sup> OPU Tube is breathable material with no VOC release after opening. After opening the sealing, the tube can be directly put into use.

Although it can be filled up to 14 ml, the recommended volume for use is between 0.5 ml to 13ml. Follow the scale on the tube.

The cap can be loosely put over the tube for keeping the gas changing. The cap can also be pushed down thoroughly for tight sealing.



Discard after use.

### Storage

Store at room temperature.

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## Product: Oosafe® Andrology Tube

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Description (volume) (ml)	Prod. No.	Qty/pc	Qty/cs
5ml, Andrology Tube	OOPW-AT10	10	500

### Intended use

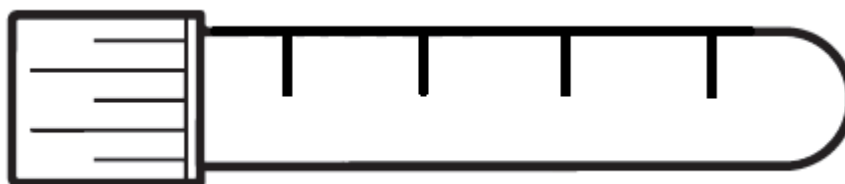
Oosafe® Andrology Tube is suitable for andrology use and small volume sample collection.

### Handling

The package of Oosafe® Andrology Tube is breathable material with no VOC release after opening. After opening the sealing, the tube can be directly put into use.

Although it can be filled up to 5 ml, the recommended volume for use is under 4 ml. Follow the scale on the tube.

The cap can be loosely put over the tube for gas changing. The cap can also be pushed down thoroughly for tight sealing.



Discard after use.

### Storage

Store at room temperature.

Additional information:

Oosafe® Plasticware instructions for use are made according to the requirements of Directive 98/79/EC and supplement information provided on the labels of the products. These instructions for use are issued by taking into account the training and knowledge of the potential users.

Version LOG:

Version No.	Language	Date of revision	Originators Name
Instructions for Use 2014	EN	01.01.2014	Mette Munk
PW-IVF- UM-17-02-2015/EN	EN	17.02.2015	Inesa Nielsen
PW-IVF- UM-01-08-2015/DK	DK	01.08.2015	Inesa Nielsen
PW-IVD- IFU-16-02-2017/EN	EN	16.02.2017	Qi Wei
PW-IVD-IFU-24-04-2017/EN	EN	25.04.2017	Qi Wei

Explanation of the symbols on the labels according to the standard ISO 15223-1:20013:



Sterilized using irradiation



Do not reuse



Batch Code



Conformity marking



Consult instructions for use



Manufacturer



Use by

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Revised version PW-IVD-IFU-25-04-2017/EN

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