

OOSAFE® 60 MM DISH, LABEL AREA GRIP *Volume 25ml*

Suitable for different applications

Single Pack

240 pcs/case

Product ID:
OOPW-ST02



Multipack

10 pcs/pack,
500 pcs/case

Product ID:
OOPW-ST03



OOSAFE® 100 MM DISH *Volume 105ml*

Perfect for big volume needs

Single Pack

70 pcs/case

Product ID:
OOPW-HD01



Multipack

10 pcs/pack,
250 pcs/case

Product ID:
OOPW-HD10



OOSAFE® SPERM COLLECTION CUP

OOSAFE® CENTRIFUGE TUBE

OOSAFE® OPU TUBE

OOSAFE® ANDROLOGY TUBE

Wide opening for easy sampling ● *Volume 80ml*

Volume 15ml

Volume 14ml

Volume 5ml

Single Pack

70 pcs/case

Product ID:
OOPW-SC01



Single Pack

300 pcs/case

Product ID:
OOPW-CT01



Multipack

10 pcs/pack,
500 pcs/case

Product ID:
OOPW-OT10



Multipack

10 pcs/pack,
500 pcs/case

Product ID:
OOPW-AT10



All our plasticware products are packed in white cardboard boxes with Oosafe® logo.



SparMED ApS

Ryttermarken 2, 3520 Farum, Denmark

Phone (+45) 39 40 25 03

www.sparmed.dk



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ID: CE-IVD-02.08.18



EC – Declaration of Conformity

Manufacturer:

SparMED ApS / CVR. no.: 30898575
Ryttermarken 2, 3520 Farum, Denmark

Product:

Oosafe® Plasticware

OOPW-FW04	Oosafe® 4 Well Dish, Non-Treated Surface
OOPW-FW03	Oosafe® 4 Well Dish, Treated Surface
OOPW-SW02	Oosafe® 6 Well Dish with Straw Holder
OOPW-SW03	Oosafe® 6 Well Dish with Straw Holder
OOPW-CW04	Oosafe® Center Well Dish with two Compartments, Label Area Grip
OOPW-CW05	Oosafe® Center Well Dish with two Compartments, Label Area Grip
OOPW-IC02	Oosafe® ICSI/IMSI Dish for Sperm Selection, Label Area Grip
OOPW-IC03	Oosafe® ICSI/IMSI Dish for Sperm Selection, Label Area Grip
OOPW-ST03	Oosafe® 60mm Dish, Label Area Grip
OOPW-TF03	Oosafe® 35mm Dish, High Wall, Label Area Grip
OOPW-HD10	Oosafe® 100mm Dish
OOPW-SC01	Oosafe® Sperm Collection Cup
OOPW-CT01	Oosafe® Centrifuge Tube, 15 mL
OOPW-OT10	Oosafe® OPU Tube, 14 mL
OOPW-AT10	Oosafe® Andrology Tube, 5mL

As manufacturer, designer and distributor under our sole responsibility here with we declare that the above listed products:

- meet the Essential Requirements of IVD Medical Device Directive 98/79/EC, Annex I, as transposed into the Danish law Executive Order No.1269 of 12 December 2005;
- classified as General IVD 98/79/EC- Sterile;
- are manufactured according to the Quality Assurance Standard: ISO 9001:2015;
- sterilized according to: EN ISO 13485:2012/ AC:2012.

Date: 2nd of August 2018



Dainius Vasiliauskas
Regulatory Affairs Manager

EC DECLARATION OF CONFORMITY

MANUFACTURER: SparMED APS / CVR. No.: 30898575,
Ryttermarken 2, DK-3520, Farum, Denmark

PRODUCTS: *Oosafe® Disinfectant*

CLASSIFICATION: Class IIa, Rule 15:

Non-active medical devices for disinfecting, cleaning and rinsing of all non-invasive medical instruments

CONFORMITY ASSESSMENT: Annex II of Directive MDD 93/42/EEC

Hereby, I the authorized representative of SparMED ApS, declare that the above listed products conform to the Council Directive 93/42/EEC for Medical Devices as transposed to the Danish laws.

NOTIFIED BODY:

Name: Istituto di Ricerche e Collaudi M. Masini S.r.l
Via Moscova 11, 20017
Rho (MI), Italy

Notified Body No: **NB 0068**

Applicable Standards:

ISO 13485: 2012	Medical devices- Quality Management Systems- Requirements for Regulatory Purposes
ISO 14971:2012-	Medical Devices - Application of risk management to medical devices;
EN 14885:2015-	Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics;
ISO 10993-1:2009-	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;
EN 62366-1:2015-	Medical devices – Part 1: Application of usability engineering to medical devices;
EN 1041:2008+A1:2013-	Information supplied by the manufacturer of medical devices;
ISO 15223-1:2012	Medical devices- Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General Requirements.;

NAME / POSITION:

Onur Ozturk/ Director

DATE: 01.06.2016

SIGNATURE

