



EC – Declaration of Conformity

Manufacturer:

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

Product: Oosafe® Plasticware

OOPW-FW03	Oosafe® 4 Well Dish, Treated Surface
OOPW-FW04	Oosafe® 4 Well Dish, Non-Treated Surface
OOPW-SW02	Oosafe® 6 Well Dish with Straw Holder
OOPW-SW03	Oosafe® 6 Well Dish with Straw Holder
OOPW-CW03	Oosafe® Center Well Dish with two Compartments
OOPW-CW05	Oosafe® Center Well Dish with two Compartments, Label Area Grip
OOPW-CW08	Oosafe® Center Well Dish, Non-Treated
OOPW-IC06	Oosafe® 50 mm Dish, Thin bottom, non-Treated
OOPW-IC07	Oosafe® 50 mm Dish, Thin bottom, non-Treated
OOPW-SD04	Oosafe® Synergy Dish, Treated
OOPW-TF05	Oosafe® 35mm Dish, High Wall, Treated
OOPW-TF06	Oosafe® 35mm Dish, Non-Treated
OOPW-HD10	Oosafe® 100mm Dish
OOPW-ST06	Oosafe® 60mm Dish, Non-Treated
OOPW-SC01	Oosafe® Sperm Collection Cup, 80ml
OOPW-CT05	Oosafe® PS Centrifuge Tube, 15 ml
OOPW-OT10	Oosafe® Snap-Cap Tube, 14 mL
OOPW-AT10	Oosafe® Andrology Tube, 5mL

As manufacturer, under our sole responsibility, we declare in accordance with annex III of Directive 98/79/EC that the above listed products the ones sold in

Lot No: XXXXX **Expiry date: YYYY-XX**

- are classified as Other devices (all devices except Annex II and self-testing devices) and follow the conformity assessment procedure referred to in Annex III.
- meet the Essential Requirements listed in Annex I of Directive 98/79/EC, as transposed into the Danish law Executive Order No.1269 of 12 December 2005.

ID: CE-IVD-23.03.22

- are manufactured and sterilized in facilities accredited with EN ISO 13485:2016 and other applicable standards referred to in OOPW-10 Applied Standard List.

Date: 23rd March 2022



Karina Boserup
Person Responsible for Regulatory Compliance
SparMED ApS