



EC – Declaration of Conformity

Manufacturer:

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

Product:

Oosafe® Plasticware

OOPW-FWXX	Oosafe® 4 well dish non-treated surface
OOPW-FWXX	Oosafe® 4 well dish treated surface
OOPW-SWXX	Oosafe® 6 well dish with straw holder (non-treated surface)
OOPW-ICXX	Oosafe® ICSI/IMSI dish for sperm selection
OOPW-CWXX	Oosafe® center well dish
OOPW-TFXX	Oosafe® 35mm dish
OOPW-STXX	Oosafe® 60mm dish
OOPW-STXX	Oosafe® 60mm dish (label area grid)
OOPW-HDXX	Oosafe® 100mm dish
OOPW-SCXX	Oosafe® sperm collection cup
OOPW-CTXX	Oosafe® centrifuge tube
OOPW-OTXX	Oosafe® OPU tube
OOPW-ATXX	Oosafe® andrology tube

As manufacturer, designer and distributor under our sole responsibility herewith 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: 5th of January 2017




Dainius Vasiliauskas
Regulatory Affairs Manager