Valued customer,

We are very pleased to announce that the following products have been CE marked in conformity with the new European In Vitro Diagnostic Medical Device Regulation (IVDR, 2017/746) as class B devices:

- SpermMar Test IgG
- SpermMar Test IgG Positive and Negative Control
- SpermMar Test IgA
- LeucoScreen Plus
- HOS Test
- Fructose Test
- EpiScreen Plus

CE marking of these IVD's according to the IVDR does result in the following changes:

- Updated instructions for use:
  - a graphic overview of the methodology is added to each instructions for use.
  - Symbol glossary is added. New symbols used on the labels are:

    

    : contains biological material of animal origin

    
    : contains human blood or plasma derivatives

    
    : caution

  - Changes per product:

SpermMar Test IgG *(positive and negative control)* **SpermMar Test IgA**	• The IFUs of the SpermMar Test IgG and SpermMar Test IgA have been separated • Update of the introduction and intended purpose • Elaboration of the section on specimen collection and preparation • Update of the performance characteristics, addition of repeatability and reproducibility • Elaboration of storage and disposal information • Elaboration of the section on warnings and precautions • Update of the bibliography
LeucoScreen Plus	• Change in lay-out • Addition of intended purpose • Addition of specimen collection and warnings before use • Update of performance characteristics • Addition of disposal information • Elaboration of the section on precautions
HOS Test	• Addition of general information • Update of intended use • Addition of test principle • Addition of specimen collection and preparation and reagent preparation • Update of interpretation section, change in classification of a semen sample • Addition of limitations and performance characteristics • Update of storage/disposal and warnings and precautions

Fructose Test	• Update of general information and intended use • Addition of specimen collection and reagent preparation • Method: standard curve and samples should be prepared in duplicate • Elaboration on section for interpretation • Addition of limitations of the method • Update of performance characteristics, storage/disposal and warnings and precautions
EpiScreen plus	• Update of general information and intended use • Addition of information on specimen collection • Update of the section on calculation and interpretation of the result • Update of the performance characteristics • Update of storage/disposal and warnings and precautions

- New version of instructions for use: please consult the new instructions on the specific product page on our website: **www.fertipro.com**.
  - Updated labelling:
    - as the products are now CE-marked as class B devices, the Notified Body was involved in the conformity assessment and this is reflected in the addition of the Notified Body number to the CE symbol on the labels.
    - For SpermMar Test IgG (Positive and Negative Control) and SpermMar Test IgA: implementation of 3- layered labels.
- Other product specific changes:
  - **SpermMar Test IgG (Positive and Negative Control) and SpermMar Test IgA:**
    - New graphic design of boxes for the single and complete kits
  - **Fructose Test:**
    - The primary packaging of Reagent 1 changed from 1x50ml bottle to 2x25ml bottles. The total volume of Reagent 1 has not changed and the bottles are of the same type.
  - **LeucoScreen Plus:**
    - Bottle of Reagent 3 has changed from a 20ml bottle to a 30ml bottle. The volume in the bottle has not changed and the bottles are of the same type.
    - As a result, the size of the box of LeucoScreen Plus has also changed.
  - **HOS Test:**
    - Sterility will no longer be claimed for the HOS Test, although the manufacturing method will not change. Note that the HOS Test is an IVD and as a consequence not to be used for semen preparation during ART procedures.

Please note that VitalScreen and Spermac Stain were already CE marked in conformity with the IVDR as Class A devices in May 2022.

If additional information is required or additional registration actions in your jurisdiction(s) are required, please send your questions to **ra@fertipro.com**

COMPANY ADDRESS
FertiPro nv
Industriepark Noord 32
B-8730 Beernem / Belgium

tel. +32 (0)50 79 18 05
fax +32 (0)50 79 17 99
info@fertipro.com
www.fertipro.com

RPR Brugge
VAT BE 0448 767 035
IBAN BE 98 7374 4024 9293
BIC KREDBEBB