Valued customer,

We are very pleased to announce that FertiCult™ Aspiration medium is now CE-marked in conformity with the new European Medical Device Regulation (MDR, 2014/745).

CE marking of the product according to the MDR does result in the following changes:

- Use of 3-layered labels (For more information: see previous newsletter).
- New version of instructions for use.
- Heparin concentration has been narrowed from 2- 3.75 IU/ml to 2 -3 IU/ml.

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

FertiCult Aspiration medium was the last device that was still MDD certified, all our products are now CE marked in conformity with the MDR.

In addition to the above, the following changes are also implemented:

- **the product labels of FertiCult™ Mineral Oil and FertiCult™ High Viscosity Oil** were updated to include the viscosity parameter, which is more informative than the density parameter.
- **the functionality test of the SpermMar Test IgG and SpermMar Test IgA** has been updated to include a microscopic check of the latex bead concentration. This extra check will be added to the COA before batch release.

EU-MDR

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