Valued customer,

We are very pleased to announce that the following products are CE marked in conformity with the new European Medical Device Regulation (MDR, 2017/745).

- 10% PVP in FertiCult™ Flushing medium
- SpermFreeze™ / SpermFreeze™ SSP
- FertiCult™ Flushing medium

We also received our updated ISO 13485 certificate, which can be downloaded on our website (www.fertipro.com/quality/).

As summarized in our previous newsletter, CE marking according to the MDR does result in the following changes:

- Use of 3-layered labels (For more information: see previous newsletter)
- New version of instruction for use
- Changes for 10% PVP in FertiCult™ Flushing medium:
  - » Stricter endotoxin specification: <0.5 EU/ml
  - » Additional product specification: human sperm survival assay (% motility compared with control after 60 minutes exposure to test medium): ≥80%
- Changes for Spermfreeze™/ SpermFreeze™ SSP:
  - » Intended use does no longer include cryopreservation of testicular and/ or epididymal sperm.
  - » Sperm survival test (SST) is replaced by a human sperm survival assay (HSSA). This means no change in test method, but only a minor difference in calculation of results.
  - » SSP001 is packaged in cardboard box instead of polystyrene box.
- No specific product changes for FertiCult™ Flushing medium

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

EU-MDR

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