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).

- Sil-Select Stock™
- Sil-Select Plus™
- GAIN™ medium

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

As summarized in a 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
- Specific changes for Sil-Select Stock™ and Sil-Select Plus™:
  - » 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.
  - » Viscosity is omitted as specification
- Specific changes for GAINTM medium
  - » Additional product specification: human sperm survival assay (HSSA) (% motility compared with control after 24 hours exposure to test medium): ≥80%
  - » Intended use does no longer include swim-up or density gradient preparation

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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