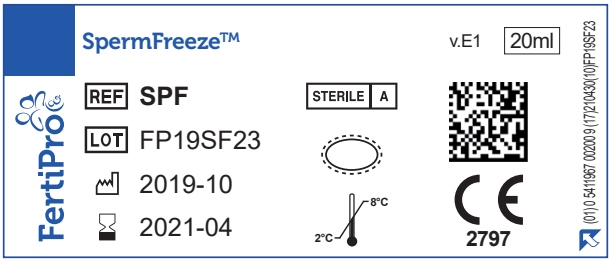
Notification to customers

We have been working very hard on our ART-media to comply with the new European Medical Device Regulation (MDR) and to get Notified Body approval based on thorough dossier reviews. We expect to receive our first MDR CE certificates very soon. But what will be the impact of MDR on you as customer?

By the end of January 2022,
we will implement some changes required by MDR:

a) **3-layered labels on each bottle because additional symbols and information are needed. Example of the typical label layout and text:**



Layer 1

Do not use if cloudy!

Contains:
15% glycerol, HEPES and
4g/L Human Serum Albumin

HSSA ≥ 80% of the control at 4h
Endotoxins < 0.25EU/mL

Layer 2

A symbol glossary is provided in the instructions for use

MD

Rx Only - Ready-to-use

FertiPro NV, Industriepark Noord 32
8730 Beernem, Belgium

Layer 3

You have probably noticed that new symbols are used on the labels, this is what they mean:

Symbol	Explanation
	**Single sterile barrier** This symbol is placed on the label of the bottles of our medical devices to indicate that content of the bottle is sterile
	**Single sterile barrier system with protective packaging outside** This symbol is placed on the label of the (cardboard) box to indicate that there is a bottle with sterile content inside the packaging.
	**Do not use if package is damaged and consult instruction for use**
	**Date of manufacture**
	**Caution** This symbol is required for all media which contain a medicinal substance, like gentamicin and human serum albumin.
	**CE symbol with Notified Body number** As we switched to BSI as Notified Body for MDR conformity assessment, the Notified Body number will switch to 2797 on the labels.

b) **Instructions for use leaflets will be updated**

c) **EmbryoFreeze/Thaw will not be CE marked in accordance with the MDR and will be discontinued.**

d) **Minor other product changes, classified per product:**

Hyaluronidase in FertiCult Flushing

- Stricter endotoxin specification: <0.5 EU/ml
- HYA001: packaged in cardboard box instead of polystyrene box

Density gradient media

- Deletion of viscosity specification
- Sperm Survival Test (SST) will be replaced by a Human Sperm Survival Assay (HSSA).
  This means no change in test method, but only a minor difference in calculation of the results.

SpermFreeze / SpermFreeze SSP

- Intended use does no longer include cryopreservation of testicular and/or epididymal sperm
- Sperm Survival Test (SST) will be 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: packaged in cardboard box instead of polystyrene box

10% PVP in FertiCult Flushing medium

- Stricter endotoxin specification: <0.5 EU/ml
- Additional product specification: HSSA (% motility compared with control after 1 hour): ≥ 80%

GAIN medium

- Additional product specification: 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.

FertiCult Flushing medium

- Additional product specification: HSSA (% motility compared with control after 24 hours): ≥ 80%

Other media

- There are no changes for FertiCult IVF medium and FertiCult Mineral oil.
- FertiVit Cooling/Warming, VitriFreeze (ES)/VitriThaw (ES), and FertiCult Aspiration medium are still in review phase with the Notified Body and information for these products will be provided later on.

IMPORTANTLY: You as distributor also need to comply with article 16 of the MDR when you do any of the following:

1. **Relabeling:** supplying of additional information or translation of information supplied by FertiPro (e.g. IFU), necessary to market the product in your country.
2. **Repackaging:** changes to the outer packaging necessary to market the device in your country.

Further reading:

- Article 16 of the EU MDR
  https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=CELEX%3A32017R0745
- MDCG 2021-26 (Q&A on repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746)
  https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_26_en.pdf
- MDCG 2021-23 (Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746)
  https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-23_en.pdf

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