

Going the extra mile

The ART of standardizing

MEDICULT
MEDIA

HUMAGEN
PIPETS

MIDATLANTIC
DEVICES



ART products, esp. IVF media, have until recently seen very little regulation, typically due to the historic lack of IVF media classification and regulation under EU directive jurisdiction.

Today, both manufacturers and clinics feel the growing demand for certification of all products and processes. Country by country, stricter regulatory requirements are steadily approaching the area of IVF. Many authorities already restrict import and/or use of unapproved products in IVF clinics.

origlio

In 2005, MediCult began a lengthy process of obtaining CE mark on all media products. This means lifting the responsibility of providing full documentation and justifying the presence of the products on the IVF market. Today, with a highly skilled regulatory department running full throttle, we are five years down the CE-route, still going strong. This illustrates the level of detail required to obtain approval for a full palette of IVF products. It is a marker of ORIGIO MediCult Media's endurance, commitment, and investment in the future of IVF.

Why should regulatory approval concern you as a customer?

Approval by authorities is your guarantee that

- the **standards** which we have set are continuously met for every product
- all components and procedures are subjected to meticulous **risk analysis**
- any claim is thoroughly backed by **scientific documentation**
- there is full **traceability** of all processes, from development to production and marketing
- no major changes in product or production can be made without **notification/approval**
- the above is regularly **scrutinized and audited** by the notified body

CE mark - What is it?

In May 2008

it was decided by the European Commission that IVF media should be regulated as Medical Devices. This was communicated in the "Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices".

This means that

IVF media and other medical devices used in ART procedures must comply with the Essential Safety Requirements as described in the European Council Directive on Medical Devices (93/42/EEC).

Marking our products

gives maximum transparency for the users, and assurance that standards for safety and health are recognized and upheld. CE is a strict approval process, demanding full documentation and traceability of all parameters, from product composition, production, instructions, to packaging labelling and shipment.

To comply

products must fulfill a number of criteria, f.ex:

- be non-toxic
- be compatible with human tissues, cells and body fluids (when applicable)
- not cause infection
- usefulness of any drug must be verified including a scientific opinion from drug authorities
- be sterile throughout its shelf life
- be clinically evaluated

This includes

reporting on and justification of:

- Composition
- Clinical use & protocols
- Raw material specification
- Risk Assessment
- Labelling



Beyond CE-marking

Quality & Purity of raw materials

In a CE-marked product, the presence of each single component and drug must be justified, and any drug must be thoroughly documented to ensure quality control.

This is where we begin to see the effects of regulations. Some of the products found in the unregulated IVF market for years are difficult to gain approval for.

Example: Protein sources

Human Serum Albumin (HSA) is the most common protein source in IVF media. Being classified as a drug, the albumin source requires a full Plasma Master File, and verification/approval from drug authorities. Very few HSA sources on the EU market comply with this.

In addition to HSA, the IVF market offers a number of poorly defined protein blends and supplement products with multiple protein sources and isotypes. It is typically difficult to obtain sufficient CMC documentation for such products, making them difficult to CE mark.

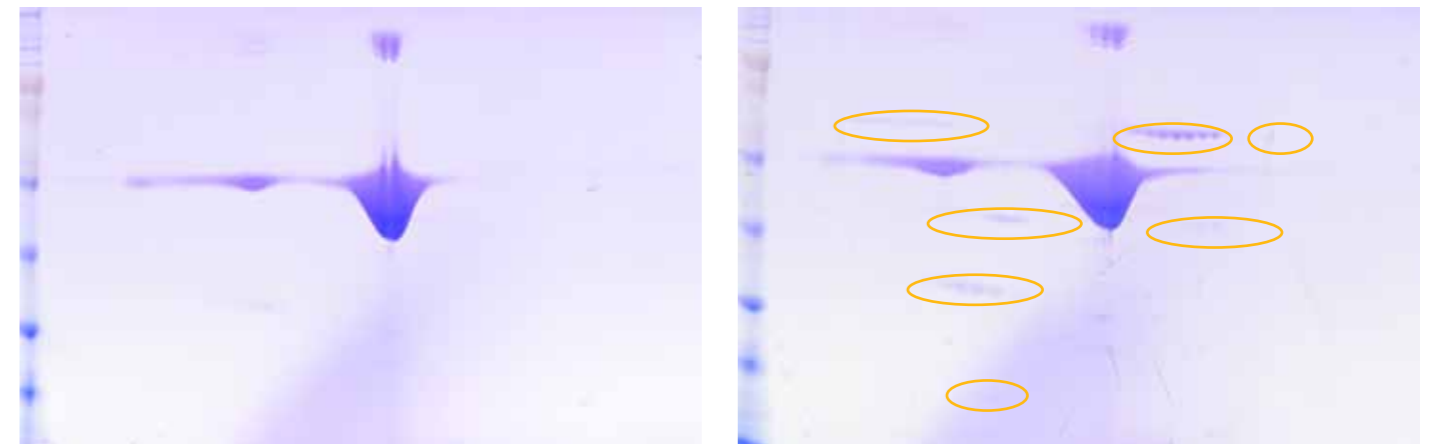


Figure 1. A comparison 2D plot of an approved Human Albumin Solution source (left) and a typical protein supplement as provided by several IVF suppliers (right). The multiple undefined proteins present cannot be fully documented and thus not approved.

Example: Towards physiological denudation

In other products, we strive to provide safer, purer products, exceeding the demands of CE documentation.

In oocyte denudation products, the active component is a single enzyme, Hyaluronidase, which breaks the hyaluronic bonds in the cumulus-oocyte complex.

All denudation products on the market today are testicular animal extracts, with the exception of ICSI Cumulase®.

ICSI Cumulase® is a recombinant product, is clear of all impurities, and contains a human hyaluronidase, the same enzyme which is present naturally in the human body.

The result is a physiological product which retains full efficiency but at the same time is the mildest, safest denudation product available on the market.

For Your Peace of Mind

While laborious for all parties, clinics and manufacturers alike, the growing regulation of medical devices and clinical practices is a manifestation of the progress in ART.

Striving for the highest degree of purity and safety, and abandoning outdated practices, is one of the basics of driving IVF into the future.

By fulfilling our part, your clinic can confidently focus on what you do best – making babies.



ORIGIO a/s
Knardrupvej 2,
2760 Måløv
Denmark

Tel: +45 46 79 02 02
Fax: +45 46 79 03 02
customerservice.medicult@origio.com
www.origio.com