

Tools for tissue engineering

To whom is this news bulletin applicable?

Manufacturers developing and producing equipment for the procurement, handling, culture or storage of cells and tissues that may be used in Advanced Therapy Medicinal Products.

With the adoption of the new Regulation on Advanced Therapy Medicinal Products the European Parliament has paved the way for the market authorization of new and innovative therapies for the benefit of all patients, not only those with currently untreatable diseases. The term Advanced Therapeutics has been coined for products such as human tissue engineering products, gene therapeutics and somatic cell therapeutics.

Special labware is used for the procurement of human cells and tissue for the manufacture of Advanced Therapeutics. As this equipment is in intimate contact with living cells or tissues, and the final product generally cannot be sterilized by routine techniques, this material needs particular attention with regard to biological safety aspects (e.g. biocompatibility and sterility).

Most of the devices used for the handling of cells or tissues have been utilized in research laboratories for many years. However, the material has been applied for in vitro use only.

It was not intended for use in conjunction with cells and tissue that are to be implanted in a patient.

The Directive 2006/86/EC asks for some special requirements with regard to the equipment utilized for the handling of cells. Medical devices are to be used for this purpose whenever possible. The classification of the equipment as medical device depends on the intended use as defined by the manufacturer.

What are the services provided by us?

You may contact us for discussion on the best strategy for certification of your product. TÜV SÜD Product Service GmbH brings together the scientific resources of over 200 experts for all types of medical devices and in vitro diagnostics. The successful application for market authorization of medical devices depends on well-planned strategic decisions and preparation of the documentation to be submitted. We will provide resources and expertise for rapid market access.

Links to informative websites:

<http://www.emea.eu.int/>

<http://www.zlg.de/>

<http://www.ich.org/>

<http://www.ghrf.org>

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