

## ***Non-compliance with Swiss and European regulations on medical devices of the intraocular iris implants NewIris, NewColorIris and BrightOcular***

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Swissmedic has been informed that a limited number of surgical procedures consisting of implanting coloured artificial irises for cosmetic purposes have been carried out in Switzerland.

These implants, manufactured by the companies Kahn Medical Devices, Corp., Panama (NewIris) and Stellar Devices LLC, New York (BrightOcular), do not carry the CE marking and as a result do not comply with the Ordinance on medical devices (ODim RS 812.213) or European Directive 93/42/EEC concerning medical devices. According to information from Kahn Medical Devices, Corp., other iris implants without the CE marking bearing the name NewColorIris are also on the market.

These implants, according to the information available on the manufacturers' websites, are also intended to alleviate diseases or trauma of the iris, for example in patients suffering from coloboma or in albino patients.

In view of the claims made by the manufacturers, in particular with regard to alleviating damage or disabilities, these implants must therefore be regarded as medical devices. They correspond to the definition in article 1 of the Ordinance on medical devices.

These three types of implant cannot therefore be placed either on the Swiss or the European market. The manufacturers have been informed of this.

Taking into account patient safety, Swissmedic is therefore anxious to make it clear that the use of these three types of implant by clinics, hospitals and ophthalmologists is prohibited as long as these products do not meet the requirements of the legislation on medical devices.

However, in accordance with article 9 paragraph 4 of the Ordinance on medical devices, Swissmedic may, on a case-by-case basis, grant exemptions if the implants serve to remedy a permanent deterioration in visual function, if no compliant medical device is available for the indication concerned and if their use is limited to individual cases.

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Further information by Swissmedic on medical devices is available at [www.swissmedic.ch/md.asp](http://www.swissmedic.ch/md.asp).

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