



## EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

**Full Quality Assurance System**

**Certificate Number: 2195-MED-1336402**

**Manufacturer:** «GRAND-Cryo» LLC  
Varshavskoye Shosse 125, Bld. 1,117587,Moscow, Russia

**Product Category(ies):** Cryotreatment Equipment

**Type(s)/Model(s):** Cryocapsule ICEQUEEN

**Final Report No:** 2195-MED- 1312014

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II(excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product category(ies) and accessories and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC.

Szutest must be informed of any significant changes in the design and/or construction of the product category(ies).

***This EC certificate is valid till 2018.12.29***

Istanbul, 2013.12.30  
Rev.01, 2014.01.13



Mehmet İŞIKLAR  
General Manager

