



EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED- 391426801

Manufacturer: TM Global Co., Ltd.
28, Digital-ro 33-gil, Guro-gu, Seoul 152 - 769, Korea

Product(s): Sterile Single Use Polydioxanone Suture with Needle

Model(s): TM, TMS

Final Report No: 2195-MED-1409003

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, 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(s) 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(s).

This EC certificate is valid till 2019-09-24

Istanbul, 2014-09-25



Mehmet Işıklar
General Manager

