



Product Service

# EC Certificate

## Production Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 12 12 46994 010

**Manufacturer:** TSK Laboratory, Japan  
2-1-5 Hirayanagi-cho  
Tochigi-Shi, Tochigi-Ken  
328-0012 JAPAN

**EC-Representative:** EMERGO EUROPE  
Molenstraat 15  
2513 BH The Hague  
THE NETHERLANDS

**Product Category(ies):** Disposable Biopsy Needles,  
Disposable Access Needles and  
Disposable Hypodermic Needles

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** TNQ235008551A

**Valid from:** 2013-03-21  
**Valid until:** 2018-03-20

Hans-Heiner Junker

**Date,** 2013-03-13



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Facility(ies):**

**TSK Laboratory, Japan Soja No.1 Factory  
1485-11, Soja-machi, Tochigi-Shi, Tochigi-Ken,  
328-0002 JAPAN**