

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** **CE 01085**  
**Issued To:** **Sofic**  
**3 Rue Jean-Jacques Rousseau**  
**B. P. 282 - Aussillon**  
**Mazamet Cedex**  
**81207**  
**France**

In respect of:

**The design, development and manufacture of sterile and non-Sterile single use devices: medical and dental needles for hypodermic injections; medical and dental safety devices for hypodermic injections.**

**For those aspects related to securing and maintaining sterility in the manufacture of Sterile Single Use Handle for Protective Injection Device.**

**For scope translation in French refer to supplementary page**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1995-12-12**

Date: **2020-04-16**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.  
This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 01085

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In the event of any conflict between the English and French text, the English text shall prevail.

Conception, développement et fabrication de dispositifs stériles ou non stériles, à usage unique: Aiguilles pour injections hypodermiques à usage médical et dentaire; Dispositifs sécurisés pour injections hypodermiques à usage médical et dentaire. Poignées stériles à usage unique pour dispositifs d'injections sécurisés, pour tous les aspects relatifs à la stérilisation et à son maintien

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