

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****Aussillon****Mazamet Cedex****81207****France**

In respect of:

See certificate scope 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 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **12 December 1995**Date: **30 April 2015**Expiry Date: **25 April 2020**

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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.

Certificate No: CE 01085

Certificate Scope:

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

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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Sterigenics SAS 8 Rue Parmentier 60290 Rantigny France	ETO Sterilization
Subhlaxmi Enterprises G/13, 1st Floor, Shreyas CHS Ltd. Hoechst Colony, Guru Govind Singh Rd. Amar Nagar, Mulund (W) Mumbai 40 00 82 Maharashtra India	Manufacture Packaging
Synergy Health Däniken AG Hogenweidstrasse 6 CH-4658 Daniken Switzerland	Gamma Sterilization

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Subcontractor:

Service(s) supplied

Synergy Health Marseille
(Marcoule)
Lieu dit Combe Bertrand
RD 138
CHUSCLAN
30200
France

Gamma Sterilization

SYNERGY HEALTH MARSEILLE
MIN 712 Les Arnavaux
13323 Marseille Cédex 14
France

Gamma Sterilization

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
12 December 1995	-	First Issue
7 February 2000	-	Griffith Micro Science address change. Gammaster Ireland removed and Gammaster Provence added as subcontractors. Richard Semark's report #444907
18 April 2005	-	Five year renewal and reissue of certificate in new format. Clarification of scope. Gammaster name change to Isotron. Griffith Micro Science name change to Sterigenics
27 February 2008	7172703	Extension to scope to add "hypodermic needles", addition of "Sterigenics France" as a sterilization subcontractor activity and clarification of certificate scope
26 April 2010	7510354	Amendment to customer address. Isotron France S.A.S address change. Re-clarification of certificate scope. Additional translation of scope into French. Five year certificate renewal
04 August 2010	7524693	Extension to scope to include "For those aspects related to securing and maintaining sterility in the manufacture of Sterile Single Use Handle For Protective Injection Device" and addition of 'Subhlaxmi Enterprises', India to list of significant sub contractors for packaging and manufacturing sub contractor activities.

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Date	Reference Number	Action
14 October 2013	8067618	Add Gamma Sterilisation sub-contractor: "Synergy Health Daniken AG, Hogenweidstrasse 6, 4658 Daniken, Switzerland" Amend existing sterilisation sub-contractor (ISOTRON FRANCE SAS) to: "SYNERGY HEALTH MARSEILLE, MIN 712 – LES Arnavaux, 13323 MARSEILLE CEDEX 14, France" Clarification of Type of Sterilisation for subcontractors.
10 April 2014	8135663	Addition of Gamma Sterilisation sub-contractor "Synergy Health Marseille (Marcoule)" for contract irradiation service.
30 April 2015	8295595	Certificate Renewal Removal of "Sterigenics SAS, Avenue de Lossburg, 69480 Anse France" for ETO Sterilization Correction to "CHUSCLAN" for Synergy Health Marseille (Marcoule)