

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 554167**
Issued To: **KITAZATO Medical Co., Ltd.**
Shibakoen Building
1-1-8 Shibadaimon,
Minato-ku,
Tokyo
105-0012
Japan

In respect of:

The manufacture of sterile oocyte pickup needle, embryo transfer catheter and intrauterine insemination catheter

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

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Gary Fenton, Global Assurance Director

First Issued: **17 October 2009**

Date: **24 October 2014**

Expiry Date: **23 October 2019**

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Page 1 of 1

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

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Japan

Subcontractor:	Service(s) supplied
Dibimed-Biomedical Supply, S.L. C/ Luis Buñuel 1 - Oficinas Pta. 4 46015 Valencia Spain	EU Representative
Radia Industry Co., Ltd 168 Ooyagi Takasaki Gunma 370-0072 Japan	Gamma Sterilization
Steri-Tech Co., Ltd 5-13-1 Hanasaki Kazo-shi Saitama-ken 347-0032 Japan	ETO Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 554167**
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Date	Reference Number	Action
17 October 2009	7447401	First issue
01 August 2014	8192583	Administrative correction of client name from "Kitazato" to "KITAZATO". Change of client address from 2-15-12 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan to Shibakoen Building, 1-1-8 Shibadaimon, Minato-ku, Tokyo 105-0012, Japan
24 October 2014	8225541	Addition of "sterile" to certificate scope. Addition of significant subcontractor Steri-Tech Co., Ltd. Certificate renewal

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Page 1 of 1

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EC Declaration of Conformity



Manufacturer: BRIDEA MEDICAL,
Govert Flinckstraat 87A,
1072ED Amsterdam

European Representative: Not Applicable

Product: Disposable Gynecological Speculum

Type / Model(s): Orchid Line

Classification: Class I (annex IX, rule 5, first indent)

Conformity Assessment Route: Annex VII (article 11, paragraph 5)

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC (MDD) for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied: EN 980:2008
EN 1041:2008
EN ISO 10993-1:2009
EN-ISO 14971:2009

Notified Body: Not Applicable

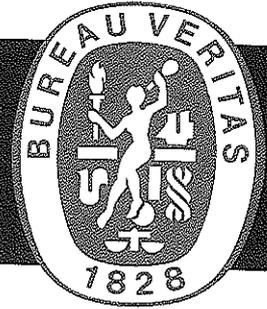
Place, date of issue:

Signature:

Name: B. Roeloffs

Position: Director BRIDEA Medical

BUREAU VERITAS
Certification



CE Certificate

Issued to

LABORATOIRES GYNEAS SARL **(member of NOVOMED Group SA)**

Head office:

7 rue de Thionville, 75019 Paris, FRANCE

Operative site:

Z.A. Charles de Gaulle – 14 rue Ferdinand de Lesseps,
95190 Goussainville, FRANCE

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC as amended

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product type:	Sterile gynecological CUSCO speculum
Model:	01.200L, 02.300L, 02.301L, 02.302L, 02.303L, 02.304L
Class:	Is

Reference BV practice: ZIG. N. 60462561

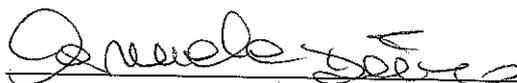
Certification cycle start date: **31 July 2016**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **30 July 2019**

Original certification date: **21 November 2014**

Certificate N. **IT269480**

Rev. N 1 of: 31 July 2016


CARMELA DE FEO- Technical Committee Coordinator

This certificate is issued by Bureau Veritas Italia S.p.A. Via Miramare, 15 - 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

BUREAU VERITAS
Certification



CE Certificate

Issued to

LABORATOIRES GYNEAS SARL (member of NOVOMED Group SA)

Registered Site:

7 rue de Thionville, 75019 Paris, FRANCE

Operative site:

**Z.A. Charles de Gaulle – 14 rue Ferdinand de Lesseps,
95190 Goussainville, FRANCE**

Bureau Veritas Italia S.p.A. certifies that the Production Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC as amended

(according to Annex V)

In relation to the following products

Product type:	Sterile device for endometrial biopsy brush
Model:	02.125, 02.126, 02.127
Class:	Is

Reference BV practice: ZIG. N. 60462561

Certification cycle start date: **08 March 2017**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **30 June 2019**

Original certification date: **08 March 2017**

Certificate N. **IT273539**

Rev. N 1 of: **08 March 2017**


ANDREA FILIPPI – Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Via Miramare, 15 - 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370



FARCO-PHARMA

FARCO-PHARMA GmbH, Postfach 101445, 50454 Köln

Konformitätserklärung
Declaration of Conformity

CE 0197

Wir, die Farco-Pharma GmbH, Pharmazeutische Präparate in Köln, erklären in alleiniger Verantwortung, dass alle von uns während der Gültigkeit dieser Erklärung in Verkehr gebrachten Chargen der *We, Farco-Pharma GmbH pharmazeutische Präparate in Cologne, being solely responsible, declare herewith, that all lots placed on the market by us while this declaration is valid of the following*

Medizinprodukte: Sterile Gleitgele
Medical Devices: Sterile lubricants

mit der Bezeichnung: ExEm® for gynaecological intracavity ultrasound imaging
and the product name:

Klasse I s nach Regel 5
Class I s according to rule 5

den einschlägigen Bestimmungen der Richtlinie 93/42/EWG über Medizinprodukte vom 14.06.1993 und der EN ISO 13485:2012+AC:2012 entsprechen. Die EU-Genehmigung nach Anhang V, auf deren Basis diese Erklärung abgegeben wird, trägt die Registrier-Nr. DD 60090532 0001 und ist gültig bis zum 12. Januar 2019.

are conforming to the Medical Device Directive 93/42/EEC dated June 14th, 1993 and EN ISO 13485:2012+ AC:2012. The EC-Approval according to Annex V, on which basis this declaration is made, bears the Registration No. DD 60090532 0001 and is valid thru January 12th, 2019.

Das Design Dossier, Stand vom 23. Oktober 2013 und aufbewahrt beim Hersteller, sowie das QM-System des Herstellers und des Sterilisationsbetriebes sind von der Benannten Stelle (0197), der TÜV Rheinland LGA Products GmbH, Tillystraße 2 in 90431 Nürnberg zertifiziert.

The Design Dossier, version from October 23th, 2013 and kept at the manufacturer's site, as well as the quality management system of the manufacturer and the sterilisation facility are certified by the Notified Body (0197) of the TUV Rheinland LGA Products GmbH, Tillystrasse 2 in 90431 Nuremberg, Germany.

Diese Erklärung ist gültig bis 12. Januar 2019.

This declaration is valid thru January 12th, 2019.

Köln, den 20. Januar 2014
Cologne, January 20th, 2014

Kai Tobien
Geschäftsführer
Managing Director

i. A. Kornelia Ely-Koort
Regulatory Affairs

FARCO-PHARMA GmbH Pharmazeutische Präparate

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Bankverbindung: Deutsche Bank AG Köln, BLZ 37070060, Konto-Nr.: 190 010 900, BIC: DEUTDE33XXX, IBAN: DE25 3707 0060 0190 0109 00,
Commerzbank AG Köln, BLZ 370 400 44, Konto-Nr.: 5 082 334, BIC: COBADEFF370, IBAN: DE81 3704 0044 0508 2334 00,
Amtsgericht Köln, Register-Nr.: HRB 5138, Geschäftsführer: Kai Tobien (Vorsitz), Friedrich Neukirch