

2019-07-08 prumlo

**UAB „ViaMedPharma“**

*(pranešimą teikiančio asmens pavadinimas) (name of person the applicant)*

Lietuva, Pilaitės pr. 16, LT04352 Vilnius, Tel.: +37052623070 Faksas +37052137563,  
ema@viamedpharma.lt

*(asmens duomenys: šalis, adresas, telefonas, faksas, el. paštas) (contact details country, address, phone, fax number)*

Valstybinei akreditavimo sveikatos  
priežiūros veiklai tarnybai prie  
Sveikatos apsaugos ministerijos

For State Health Care Accreditation Agency  
under the Ministry Of Health  
of the Republic of Lithuania

**DUOMENYS APIE IIA, IIB, III KLASĖS IR PAGAL UŽSAKYMĄ GAMINAMAS  
AKTYVIAŠIAS IMPLANTUOJAMĄSIAS MEDICINOS PRIEMONES (PRIETAISUS)  
INFORMATION ABOUT IIA, IIB, III CLASS AND CUSTOM MADE ACTIVE  
IMPLANTABLE MEDICAL DEVICE**

2019 m. Liepos 8 d.  
*(data)(date)*

Vilnius

*(sudarymo vieta)(place)*

**1. Duomenis teikia / Notification presented by: (žymėti / mark „X“)**

Gamintojas / Manufacturer

Igaliotasis atstovas EEE/Authorized representative EEA

Importuotojas / Importer

Platintojas / Distributor

x

Pranešimas apie duomenų pasikeitimą /  
Notification about changes of information

Keičiamos Duomenų formos registracijos numeris  
ir data / Date and number of first notification

**2. Duomenys apie gamintoją (pavadinimas, adresas, šalis):**

**Manufacturer's information** (name, address, country):

Kitazato Corporation Tokyo Office, Shibakoen Building, 1-1-8 Shibadaimon, Minato-ku, Tokyo 105-0012 Japan

**3. Duomenys apie įgaliotąjį atstovą (pavadinimas, adresas, šalis) – jei taikoma:**

**Authorized representative's information** (name, address, country) – if relative:

**4. Duomenys apie medicinos priemonę (prietaisą) / Information about medical device:**

**4.1. bendrinis pavadinimas / generic name** Oocyte picup needle – Kiaušialąsčių paėmimo adata

**4.2. modelis /model** Opu Needle

**4.3. klasė / class** (žymėti / mark „X“): IIA x IIB ☐ III ☐

4.4. pagal užsakymą gaminama aktyvioji implantuojamoji medicinos priemonė (prietaisas) / custom made active implantable medical device ☐

4.5. paskelbtosios įstaigos numeris / Notified body's number: 2797

Patvirtinu, kad pateikti duomenys yra teisingi. Duomenims pasikeitus, apie tai bus pranešta per 14 kalendorinių dienų.

I confirm that presented information is correct. In case this information is changed, you will be notified in 14 days.

Viešųjų pirkimų specialistė – Teisininkė

\_\_\_\_\_  
(pareigų pavadinimas / position)



\_\_\_\_\_  
(parašas / signature)

Ema Dalikaitė

\_\_\_\_\_  
(vardas ir pavardė / name)

# EC Certificate - Production Quality Assurance

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

**No.**

**CE 554167**

**Issued To:**

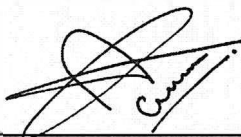
**Kitazato Corporation Tokyo Office  
Shibakoen Building  
1-1-8 Shibadaimon,  
Minato-ku,  
Tokyo  
105-0012  
Japan**

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2009-10-17**

Date: **2024-02-20**

Expiry Date: **2024-10-23**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780  
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.  
A member of BSI Group of Companies.



# 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:

Certificate No: **CE 554167**  
Date: **2019-02-20**  
Issued To: **Kitazato Corporation Tokyo Office**  
**Shibakoen Building**  
**1-1-8 Shibadaimon,**  
**Minato-ku,**  
**Tokyo**  
**105-0012**  
**Japan**

Subcontractor:	Service(s) supplied
Dibimed-Biomedical Supply, S.L. C/Luis Buñuel 1 – Oficinas Puerta 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**  
 Date: **2019-02-20**  
 Issued To: **Kitazato Corporation Tokyo Office**  
**Shibakoen Building**  
**1-1-8 Shibadaimon,**  
**Minato-ku,**  
**Tokyo**  
**105-0012**  
**Japan**

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
14 March 2017	8689403	Change of company name from 'KITAZATO Medical Co., Ltd.' to 'Kitazato Corporation Tokyo Office' Change of EU representative address from 'C/Luis Buñuel, 1-Oficinas Pta.4 46015 Valencia, Spain' to 'C/Luis Buñuel, 1-Oficinas Puerta 2 46015 Valencia, Spain'
19 December 2018	8958275	Change of EU representative address from 'Dibimed-Biomedical Supply, S.L., C/Luis Buñuel, 1 – Oficinas Puerta 2, 46015 Valencia, Spain' to 'Dibimed-Biomedical Supply, S.L., C/Luis Buñuel, 1 – Oficinas Puerta 4, 46015 Valencia, Spain'.
Current	9719674	Traceable to NB 0086.

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