

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60130386 0001

Report No.: 28417154 002

Manufacturer: RAFFIN MEDICAL S.A.
746 Route de Sarcey
69490 Saint Romain de Popey
France

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60110346 0001

Expiry Date: 2023-03-20

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-07-25

Date: 2018-07-25

Notified Body

Maciej Sciera

Maciej Sciera



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60130386 0001
Report No.: 28417154 002

Manufacturer: RAFFIN MEDICAL S.A.
746 Route de Sarcey
69490 Saint Romain de Popey
France

Products included:

- Instruments
- Swabs
- Anaesthesia kits
- Application kits
- Delivery kits
- Dressing kits
- Infusion kits
- Surgical procedure kits
- Suture kits
- Urinary probing kits

Date: 2018-07-25

Notified Body

Maciej Sciera
Maciej Sciera



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60130386 0001
Report No.: 28417154 002

Manufacturer: RAFFIN MEDICAL S.A.
746 Route de Sarcey
69490 Saint Romain de Popey
France

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Bandages
- Gauze fabric and swabs
- Gallipots/trays
- Instruments
- Anaesthesia kits
- Application kits
- Gynaecologic pads
- Hygiene equipment
- Delivery kits
- Dressing kits
- Infusion kits
- Surgical procedure kits
- Suture kits
- Urinary probing kits

Date: 2018-07-25

Notified Body

Sciera Maciej
Maciej Sciera



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: DD 60130386 0001
Report No.: 28417154 002

Manufacturer: **RAFFIN MEDICAL S.A.**
746 Route de Sarcey
69490 Saint Romain de Popey
France

Sites included:

TEC MAROC
Carriere Ben Adib Km 22
Dar Bouazza
20150 Nouaceur, Maroc
Activity: Manufacture

TEC MAROC
Zone Industrielle du Sahel
Lot n°1
26400 Had Soualem, Maroc
Activity: Manufacture

Raffin Medical Afrique
Lot 29 Z.I Had Soualem, Maroc
Activity: Manufacture, ethylene oxide sterilization

Date: 2018-07-25

Notified Body

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