

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148231 0001

Report No.: 28239475 014

Manufacturer: TAISSIS CONCEPT SRL
Ion Ticaloiu Street no. 17
115100 Campulung, Arges
Romania

Products: (see attachments for scope included)

Replaces EC Certificate. Registration No. HD 60147843 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-04-16

Date: 2020-04-16

Notified Body



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

**Attachment to
Certificate**

Registration No.: HD 60148231 0001
Report No.: 28239475 014

Manufacturer: **TAISSIS CONCEPT SRL**
Ion Ticaloiu Street no. 17
115100 Campulung, Arges
Romania

Scope included:

- Sterile paraffin dressing
- Cold therapy devices
- Cleaning / irrigation solution for ENT
- Sterile single-use dialysis on-off kits
- Sterile surgical kits and instruments for single use
- Sterile single-use dressing kits
- Sterile polyurethane with silicone dressings
- Sterile polyurethane with hydrocolloid dressings
- Sterile impregnated compresses with hydrocolloid
- Sterile impregnated dressing and bandages with hydrogel

Date: 2020-04-16

Notified Body


Dr. T. Kießling



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60148231 0001
Report No.: 28239475 014

Manufacturer: **TAISSIS CONCEPT SRL**
Ion Ticaloiu Street no. 17
115100 Campulung, Arges
Romania

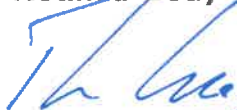
Scope included:

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

- Sterile gauze nonwoven compresses
- Sterile plasters and strips
- Sterile surgical gowns
- Sterile surgical drapes
- Sterile universal drapes kits
- Sterile cardiology surgical drapes kits
- Sterile neurosurgery surgical drapes kits
- Sterile orthopaedics surgical drapes kits
- Sterile urology surgical drapes kits
- Sterile obstetrics-gynecology surgical drapes kits
- Sterile single-use urinary kits
- Sterile single-use Enema kits
- Sterile single-use obstetrics-gynecology kits
- Sterile hydrogel solution in sprays and unidoses envelopes

Date: 2020-04-16

Notified Body


Dr. T. Kießling

