

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**TAISSIS CONCEPT SRL**  
**Ion Ticaloiu Street no. 17**  
**115100 Campulung, Arges**  
**Romania**

has established and applies a quality management system for medical devices  
for the following scope:

**(see attachment for scope included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-05-16  
Certificate Registration No.: SX 60127255 0001  
An audit was performed. Report No.: 28239475 002  
This Certificate is valid until: 2019-03-30

Certification Body



Date 2018-05-16

*Maciej Sciera*  
Maciej Sciera



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

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60127255 0001  
**Report No.:** 28239475 002

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

**Scope:**

Design and development, manufacture and distribution of active and non-active medical devices for wound care and first-aid, surgical care, ENT (ear/nose/throat) solutions and gynecology solutions;  
Provision of EO gas sterilization services according to ISO 11135:2014

**Certification Body**



**Date: 2018-05-16**

*Maciej Sciera*  
**Maciej Sciera**

