

# 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 13485:2016**

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

Effective Date: 2019-09-30  
Certificate Registration No.: SX 60140162 0001  
An audit was performed. Report No.: 28239475 007  
This Certificate is valid until: 2020-10-04

Certification Body



Date 2019-09-30

  
Maciej Sciera



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

**Attachment to  
Certificate**

**Registration No.:** SX 60140162 0001  
**Report No.:** 28239475 007

**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: 2019-09-30**

*Maciej Sciera*  
**Maciej Sciera**

