

# EC Certification

## Intertek

**FULL QUALITY ASSURANCE SYSTEM**  
**Directive 93/42/EEC for Medical Devices, Annex II excluding (4)**

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

## PLASTI-MED, PLASTIK MEDİKAL ÜRÜNLER SANAYİ VE TİCARET LTD ŞTİ

Deri Organize Yan San, Gel Alani, YA/11, Aydinli-Tuzla, Istanbul, Turkey

### NON-STERILE PRODUCTS

Oxygen masks, Nebulizer sets, High concentration oxygen masks, Nasal oxygen cannula, Nasal oxygen cannula – pediatric, Respiratory Systems and Connectors, Anaesthesia Systems and Connectors, Breathing and anaesthesia circuits  
Suction Canister, Blood gas sampling kit, Spirometer filters, Suction Bag, Karman syringe.

### STERILE PRODUCTS

Umbilical cord clamp, Poche perforator, Airway, Biopsy punch, Suction catheter, Nelaton catheter, Yankauer suction set and accessories, Aspirator connecting tube, Karman syringe and Karman Cannula, Suction Bag, Suction Canister, Drainage Bags and soft drain, Heparin Cap, extension line and Three-way stopcock, Bacterial filters, Endometrial cell sampler, Disposable oral swab, Blood gas sampling kit, Closed wound drainage systems and accessories, Spirometer filters, Arthroscopy set Y (T.U.R.), Arthroscopy set with manual pressure pump (T.U.R.), Breathing and anaesthesia circuits.

**Certificate Number:** 627 CE  
**Initial Certification Date:** 18 June 2004  
**Certificate Effective Date:** 01 July 2015  
**Certificate Expiry Date:** 17 June 2019



*Barry A. Fitch*  
AMTAC Certification Services Limited, Milton Keynes, UK  
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at [certificate.validation@intertek.com](mailto:certificate.validation@intertek.com) or by scanning the code to the right with a smartphone.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.  
AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.