EC Certification

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 MEDIKAL ÜRÜNLER SANAYI VE TICARET LTD ŞTI

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.

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Date: 2019.03.19 15:48:17 EET
Reason: MoldSign Signature
Location: Moldova

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
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