



Management Systems Certification Body
Institute for Testing and Certification, Inc.
trida Tomase Bati 299, Louky, 763 02 Zlin, Czench Republic

Notified Body 1023

EC Certificate Full Quality Assurance Systems: Certificate 18 0031 SJ

We assessed and certified on the basis of a performed audit that company

Heager GmbH

Friedrich -Elbert-Strabe, 111/117, 42781 Haan , Germany
Company Reg. No. : DE 295833673

has been meeting the requirement of
Annex II- excluding Section 4 of the Council

Directive 93/42 EEC

for the following products.

Class I

Medical Imaging Cameras (HUMIS, HD 8866, CHS) ✓
Medical or Surgical Display Monitors
LED Light Source with or without fiber optic cable (LED 400) ✓
Non active reusable surgical instruments
Image Management Systems & Image Recording Software

Class II a

Telescope (Laparoscope, Hysteroscope, Cystoscope, Sinuscope, Arthroscope)
Co2 Insufflator with or without smoke evacuator (Gasofiator)
Suction Irrigation Pump with or without Suction (Hysterojet) ✓
Reusable Monopolar , Reusable Bipolar Laparoscopic Instruments

The Certificate is issued on the basis of the results mentioned in Audit Report no.233404635/2018. The certificate validity is conditioned by positive results of surveillance audits, which the certified company committed to undergo. During use of the certificate, the certificate holder undertake to follow the Rules of use of the certificate.



Date of Issue: 2018-09-15
Valid until: 2021-09-14 ✓

Ing. Pavel Vaněk
Head of Certification Body